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Guidance for the Reregistration of Pesticide Products Containing EPN as the Active Ingredient

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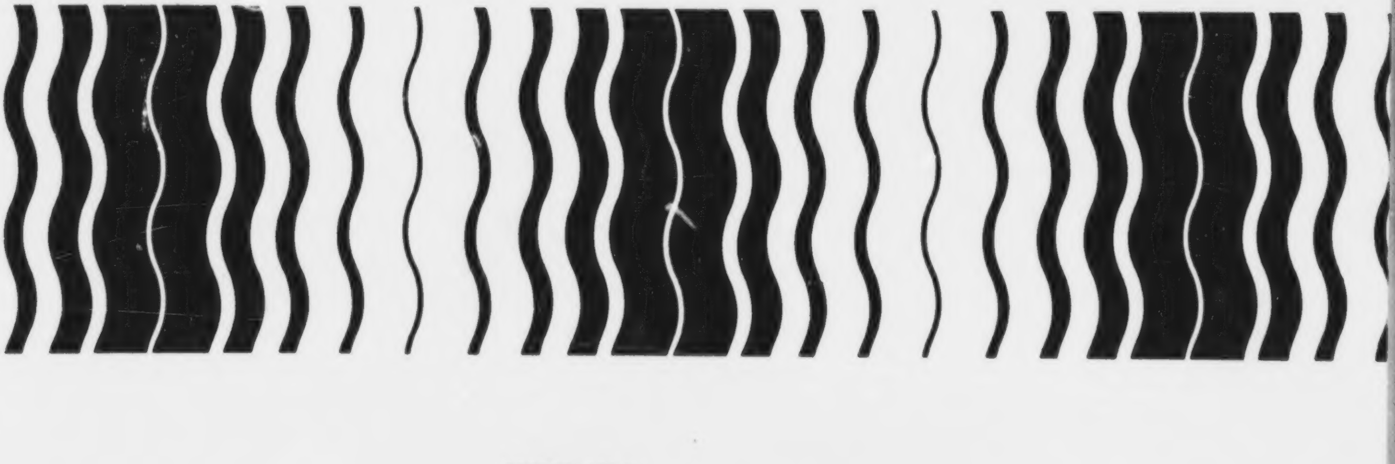

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
EPN
AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 2104-64-5

OPP SHAUGHNESSY NO. 041801

EPA CASE NUMBER 147

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

EPN is the accepted abbreviation for the chemical O-ethyl O-p-nitrophenyl phenylphosphonothioate. There is no official common name. The basic manufacturer of EPN is Nissan Chemical Works, Ltd. of Japan. There are currently no technical EPN products registered in the United States.[2]

Some identifying codes and characteristics are:

Chemical Class: non-halogenated, aromatic, phosphonothioate organophosphorus compound.

Empirical Formula: $C_{14}H_{14}NO_4P_5$

Molecular Weight: 323.3

CAS Registry No.: 2104-64-5

OPP Shaughnessy No.: 041801

The pure compound occurs as a light-yellow crystalline powder with an aromatic odor and the technical grade is a reddish-yellow oily liquid. EPN is only slightly soluble in water and is miscible with benzene, toluene, xylene, acetone, isopropyl alcohol, and methanol. EPN has a melting point of 34.5°C, vapor pressure of 0.03 mmHg at 100°C and specific gravity of 1.27 at 20°C.

B. Regulatory History

EPN was first introduced in 1949 by E. I. du Pont de Nemours and Company, Inc. In 1950 E. I. du Pont de Nemours and Company, Inc. obtained a patent for EPN (Patent Number 2503390) and the first registration and tolerances were issued for the chemical in the same year. During the ensuing years EPN has been subjected to the following regulatory actions.

1. Cancellation of Uses in The Absence of a Finite Tolerance

PR Notice 68-6 published on February 1, 1968, proposed the cancellation of use of EPN on onions in the absence of a finite tolerance or exemption.

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[2] Active registrations for technical EPN were formerly held by E. I. du Pont de Nemours, Laroche Industries, Inc., Marubeni America, J. R. Simplot Company, and Velsicol Chemical Company. However, these registrants have requested voluntary cancellation of their registrations for technical EPN in lieu of developing the data required to support the continued registration of their products.

2. Classification of Certain Use Patterns as Non-food Uses

PR Notice 68-8 published on April 24, 1968, classified certain chemical use patterns as non-food uses, allowing registration of products for these uses to continue in the absence of finite tolerances. Use of EPN as a special mosquito larvicide was classified as a non-food use.

3. Classified as Highly Toxic to Bees

PR Notice 68-19 published on November 29, 1968, classified EPN and certain other pesticides as highly toxic to bees and required the label statement, "This product is highly toxic to bees exposed to direct treatment or residues on crops. Protective information may be obtained from your Cooperative Agricultural Extension Service."

4. Specific Reentry Period Designated

On May 10, 1974, the Agency published in the Federal Register (39 FR 16890) a list of 9 pesticides designated for a specific reentry period in 40 CFR 170.3(b). EPN was one of those 9 pesticides. Pesticide products containing EPN have a reentry time of at least 24 hours, prior to which workers must wear protective clothing in order to be permitted to enter a field treated with EPN.

5. Certain Uses Classified for Restricted Use

On August 1, 1979, the Agency published a proposed rule in the Federal Register which would amend 40 CFR 162.31 by adding uses of active ingredients to be classified for restricted use under 40 CFR 162.30. Under the proposed rule, all EPN liquid and dry formulations greater than 4% and all EPN granular formulations 2% and greater would be classified for restricted use (44 FR 45218). This proposed rule was based on the risk criteria for determining a pesticide's use classification, as provided in 40 CFR 162.11 (c)(2) through 5, which require that determinations concerning the use classification of a pesticide must take into account the pesticide's existing toxicity category, the level of risk posed to humans and the environment, the adequacy of present labeling, and other hazard information.

The Agency published the final rule in the Federal Register on January 19, 1981, adding certain uses of eight active ingredients (including EPN) to the list of uses which the Agency has classified for restricted use (46 FR 5696). The final rule regarding EPN classification became effective on June 10, 1981 (46 FR 29708), whereupon all uses of EPN liquid and dry (granular and wettable powder) formulations greater than 4% were classified for restricted use.

6. Rebuttable Presumption Against Registration (RPAR)

On September 19, 1979, the Agency issued a Notice of Rebuttable Presumption Against Registration[3] of Pesticide Products Containing EPN (44 FR 54384). The Agency based the presumption against registration upon studies showing that EPN caused delayed neurotoxic effects in test animals, and was acutely toxic to aquatic organisms. The Agency also identified five other possible adverse effects of EPN for which insufficient information existed to issue a rebuttable presumption. Those effects were: (1) teratogenic effects; (2) cholinergic effects; (3) disorders of the eye; (4) possible mutagenic effects; and, (5) reductions in populations of nontarget organisms (honeybees). The existence of a data gap for oncogenic effects was also noted. In addition, the Agency noted that, when used in combination with malathion, dimethoate, or Systox, EPN had been observed to potentiate the acute toxicity of these chemicals, i.e., causes the total effect of the two chemicals to be greater than the sum of the two effects taken independently.

The EPN laboratory animal (chicken) neurotoxicity studies which formed the basis for the Agency's Special Review (RPAR) demonstrated that EPN caused many effects characteristic of organophosphate-type delayed neurotoxicity. Some of these characteristics are: a delay of from 10 to 14 days between a single effective dose and the appearance of clinical and histopathological signs; the appearance of the delayed effect well after the recovery from the acute toxicity of the compound; the appearance of abnormalities in gait which may proceed to complete paralysis and are generally irreversible; and, the destruction of nerve axons in the spinal cord and the subsequent disappearance of the myelin sheath which surrounded the lost axons. However, due to inconsistencies in those studies the Agency at that time concluded it could not use those studies to establish a NOEL for EPN delayed neurotoxic effects. Rather, the Agency used a human study, in which a NOEL of 0.1 milligrams per kilogram (mg/kg) per day was established for EPN-induced depression of plasma and red blood cell (RBC) cholinesterase levels as the most sensitive indicator for human toxicity. On that basis the Agency calculated dietary and applicator risks posed by the continued uses of EPN. (However, as explained below in Section III. A. 2., III. B. 2., and III. B. 9., data on histopathological changes in the spinal cord are more appropriate for setting a NOEL for human risk assessment purposes.)

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[3] The Agency created the Rebuttable Presumption Against Registration (RPAR) process to facilitate the identification of pesticide products (or uses thereof) which may not satisfy the statutory standard for registration, and to provide an informal procedure through which to gather and evaluate information about the risks and benefits of these products and uses. Subsequently, on November 27, 1985, the Agency published revised, final regulations (40 CFR Part 154) in which the term RPAR was changed to Special Review. A Special Review arises if a pesticide meets or exceeds any of the risk criteria set forth in the regulations.

The maximum dietary burden if EPN were used on all crops for which it was registered was calculated to be 0.016 mg/kg of body weight (bw) per day for a 60 kg person. The maximum dietary burden assumed that EPN residues existed on each commodity at the full tolerance level.

Based on tolerances for cotton, corn, and soybeans, three crops comprising the bulk of EPN useage, the sum of the dietary burdens for these crops was calculated to be 0.00036 mg/kg/day for a 60 kg individual. This calculation factored in the percent of the crop treated. Based on this exposure estimate and the oral NOEL of 0.1 mg/kg/day for blood cholinesterase inhibition in humans, an acceptable Margin of Safety (MOS) of 277 existed. The Agency's Position Document 4 stated that an acceptable MOS for cholinesterase inhibition was 10 and for delayed neurotoxicity was 100.

The Agency also calculated MOSs for all applicator groups, based on a human NOEL of 0.1 mg/kg per day for EPN cholinesterase inhibition, using a worst case and a more realistic case approach.

1. If protective clothing and a respirator are worn, applicator exposure should be limited to the dermal route. Using the worst case of 100% dermal absorption, and based on a NOEL of 0.1 mg/kg per day, MOSs were calculated as follows:

   pilots - 38
   flaggers - 1
   loaders - 4
   ground applicators - 9

   In using the worst case approach, MOSs for most applicator groups were considered unacceptable.

2. Another approach was used to reflect a more realistic risk to applicators from the use of EPN. In this approach the Agency, using acute toxicity data, estimated a dermal absorption rate for EPN to be approximately 31%. Using the 31% dermal absorption value, the following margins of safety were calculated:

pilots - 125
flaggers - 3
loaders - 13
ground applicators - 30

Using the 31% absorption value, adequate MOSs were considered to exist for all applicator groups except flaggers with regard to cholinesterase inhibition, but MOSs for the delayed neurotoxic effect were below the accepted level except as to pilots.

The Agency received a number of comments from registrants and others regarding the risks and benefits of EPN in response to the September 19, 1979 RPAR Notice. In evaluating those comments the Agency reevaluated EPN's chemistry, environmental activity and movement, toxicity, effects upon wildlife populations, and the exposure of humans and animals to EPN. The Agency also evaluated the benefits of EPN use and the effects of cancellation upon the agricultural economy.

The Agency's reevaluation confirmed that EPN produces delayed neurotoxicity in chickens but indicated that, although subtle histological effects were observed in a well-conducted test at 0.1 mg/kg per day, the toxicological significance of these effects could not be determined without additional study. The Agency's reevaluation also confirmed that EPN is acutely toxic to honeybees, causing reductions in local and regional populations of these nontarget organisms; and is acutely toxic to aquatic organisms (from the mosquito larvicide use only). The Agency's examination of use patterns in effect at that time and the potential for exposure indicated that an ample MOS existed for human dietary exposure and for applicators, with the exception of human flaggers. With regard to honeybees, the Agency determined that sufficient residues remain two to three days after application to present an acute hazard to bees. However, the Agency determined that this acute toxicity could be sufficiently mitigated with the use of appropriate labeling. Following this reevaluation of the risks and benefits of EPN, the Agency concluded the RPAR for EPN with the issuance of a Decision Document in June 1983 and the publication of its final notice of determination concluding the RPAR for EPN in the Federal Register on August 31, 1983 (48 FR 39494). The Agency's final regulatory decision on EPN at the conclusion of the Special Review (RPAR) is summarized in Table 1 below.

Table 1 - Summary of EPA's Final Regulatory Decision Concluding the RPAR for EPN

Use site	Final decision
Mosquito Larvicide use	Cancel.
All other uses	Cancel, unless the following modifications are made to the terms and conditions of registration: Human flaggers prohibited unless in totally enclosed vehicles. Standardize label requirements for protective clothing, goggles, and respirators, the phrase "protective clothing required" to appear prominently in bold type as follows: PROTECTIVE CLOTHING REQUIRED: Wear clean protective clothing, goggles, and respirators approved by NIOSH or the American National Standards Institute when applying or handling, or when reentering fields within [at least 24] hours of treatment. The following protective clothing must be worn: lightweight unlined natural rubber gloves at least mid-forearm in length; a wide brimmed waterproof hat or waterproof hood; a protective suit or coveralls of a non-permeable, non-cloth material covering the body from ankles to wrists; lightweight unlined natural rubber boots at least mid-calf in length; full-face respirators are recommended; half-face respirators and goggles are required. The following statement must appear in the "Use Directions" section of the label: "Do not apply this product when weather conditions favor drift from treated area." The following statement must appear in the "Environmental Hazards" section of the label for Wettable Powder (WP) and Emulsifiable Concentrate (EC) formulations: "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

(Table 1 continued on next page)

Table 1 - Summary of EPA's Final Regulatory Decision Concluding the RPAR for EPN (continued)

Use site	Final decision
WP and EC formulations for use on Cotton	In addition to the requirements for "All Uses", the following statement must appear in the "Use Directions" section of the label: "Do not apply to blooming cotton if bees are visiting the treatment area."
WP and EC formulations for use on Field Corn and/or Sweet Corn	In addition to the requirements for "All Uses", the following statement must appear in the "Use Directions" section of the label: "Do not apply to corn during the pollen-shed period if bees are visiting the treatment areas."
WP and EC formulations for use on Stone Fruits, Pome Fruits, and Citrus	In addition to the requirements for "All Uses", the following statement must appear in the "Use Directions" section of the label: "Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom."
All Food Uses	Reassess tolerances. Data necessary to reassess EPN tolerances will be required in the Agency's Registration Standard Review Process.
Areas for Further Consideration	The Agency identified the following areas in which data were required: Teratogenic effects. Teratogenic studies in rats and rabbits are needed. Oncogenic effects. Studies on the oncogenic potential of EPN in rats and mice are needed. Delayed neurotoxic effects. A study to explore the mechanism of "recovery" from a mild case of EPN-induced delayed neurotoxicity in an experimental species will be required. Reentry time reassessment. Data necessary to reassess the 24-hour reentry time for EPN were required.

7. Data Call In (DCI)

The Agency issued a Data Call In (DCI) Notice on May 31, 1985 requiring teratogenicity, reentry protection, and delayed neurotoxicity data. These data have been received and reviewed by the Agency and are discussed below in the Preliminary Health Risk Assessment section III. B.

The Agency issued another DCI Notice on December 19, 1986 to all EPN registrants, including the basic registrant of technical EPN, Marubeni America, Inc., for all of the data gaps identified in this registration standard. The Agency chose to proceed with the issuance of the data requirements in December 1986 without this document because the Agency had not completed its assessment of critical toxicology data which was to be incorporated into this document. This Registration Standard provides a review of these and other data and a reassessment of the RPAR regulatory decisions.

On March 26, 1987 Marubeni America presented to the Agency its decision that it would not generate and submit these required data and that it requested a voluntary cancellation of its EPN product registration. As a result of Marubeni's action, the Agency reissued the December 1986 DCI Notice on March 26, 1987 to all other remaining EPN registrants (i.e. formulators) informing them that the Agency could not exempt them from producing the required data to support continued registration of their EPN products since all the registrants of technical EPN had chosen to voluntarily cancel or suspend their EPN registrations.

C. Use Profile

EPN is a broad spectrum non-systemic, slightly persistent, contact and orally active organophosphate insecticide and acaricide that has been marketed in the United States for over 35 years. There are currently no active registrations for Technical EPN in the United States.

There are currently 5 single active ingredient products[4] and 27 multiple active ingredient products[5] registered. Single active ingredient formulations currently registered consist of:

Product Type	Percent Active Ingredient
Granular	(2% and 4%)
Wettable Powder	(25%)

Single active ingredient formulations formerly registered included:

Technical	(93%)
Formulation Intermediate	(80%)
Emulsifiable Concentrate	(2 lb/gal, 4 lb/gal, and 5 lb/gal)

(All liquid formulations and any formulation greater than 4% active ingredient are classified as restricted use pesticides).

EPN is registered for use on a variety of terrestrial food crop and terrestrial nonfood sites and can be foliarly broadcast using aerial or ground equipment. Applicators are required to be certified or under the direct supervision of applicators certified to apply EPN. Major use sites include cotton, soybeans, field corn, and pecans. Other registered uses include almonds, apples, apricots, beans (green beans, lima beans, navy beans, red kidney beans, snap beans), black-eyed peas, cherries (sweet and sour), citrus (citron, grapefruit, lemons, limes, oranges, tangelos, tangerines), corn (sweet), cowpeas, grapes, kumquats, nectarines, olives, peaches, pears, pecans, plums, prunes, sugar beets, tomatoes, walnuts, and earthworm farms.

EPN is used to control insects such as the peach twig borer, spider mites, codling moth, plum curculio, fruittree leafroller, pear psylla, cottony peach scale, Lecanium scales, olive scales, oriental fruit moth, lesser peachtree borer, peachtree borer, armyworm complex, beet webworm, thrips, tomato fruitworm, European corn borer, Mexican bean beetle, twospotted spider mite, aphids, flea beetles, leafhoppers, Lygus bugs, climbing cutworms, darkling beetles, stink bugs, citrus red mites, citrus thrips, orange tortrix, orangeworms, corn rootworms, southwestern corn borer, cabbage looper, cotton leafperferator, tomato russet mite, grasshoppers, boll weevil, bollworm, pink bollworm, tobacco budworm, grape berry moth, grape leafhopper, walnut caterpillar, hickory shuckworm, pecan weevil, may beetles, pecan leaf casebearer, pecan nut casebearer, spittlebugs, blister beetles, and corn earworm. (Refer to Appendix III, "EPA Index to Pesticide Chemicals", for usage rates, calculations of amount of active ingredient used, and complete listing of use sites and pests.)

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[4] Single active ingredient products registered include 5 under FIFRA Section 3.

[5] Multiple active ingredient products registered include 23 under FIFRA Section 3, 3 under FIFRA Section 24(c), and 1 Intrastate.

EPN was first registered for use in 1950 but was not heavily utilized until the mid to late 1970s following the cancellation of DDT. From annual usage levels in excess of four million pounds of active ingredient (A.I.), a declining trend began by 1980 as the newly developed synthetic pyrethroids started to replace organophosphates in the cotton market.

The current aggregate annual usage estimate of 975,000 pounds of A.I. is considerably less than the 1.7 to 3.2 million pounds of A.I. presented in the Agency's 1983 Preliminary Quantitative Usage Analysis. The continued future use of EPN on cotton is expected for early season applications and for years of heavy target pest infestations; future usage could increase if pest resistance develops for the pyrethroids.

Approximately 99% of the total amount of EPN use in the United States in 1985 was attributed to use on major cotton, soybeans, field corn, and pecan pests. These four use sites comprise about 91%, 3%, 5%, and <1% respectively, of the annual EPN usage. Recommended application rates range from 0.125 to 5.0 lb. active ingredient per acre (a.i./A). The percent of the four use sites treated with EPN are 3%, <1%, 7%, and <1%, respectively.

California and Federal reentry intervals of 14 days and 24 hours, respectively, have been established for EPN. (However, the Agency now has adequate data to establish interim reentry levels for all crops as detailed below in Section III. B. of this Registration Standard.)

Tolerances are established for use of EPN on certain fruit, nut, field and vegetable crops.

III. AGENCY FINDINGS

A. SUMMARY

1. Summary of Agency Conclusions

The Agency has reviewed all data currently supporting the registration of EPN. Based on the review of these data, the Agency has reached the conclusions listed below. These conclusions are presented in more detail in subsections III B, III C, and III D below.

a. EPN has been demonstrated to cause delayed neurotoxicity in the domestic hen. The effects have been expressed as ataxia and damage to the sciatic nerve and spinal nerve cord.

b. There are inadequate margins of safety (MOSs) for delayed neurotoxicity from dietary exposure to crops treated with EPN and from worker exposure associated with applying EPN and reentering treated fields.

c. EPN is acutely toxic to honeybees. Sufficient residues remain on treated crops for two to three days after application to present an acute hazard to honeybees.

As a result of this assessment under the Registration Standard process, the Agency has determined that the delayed neurotoxicity characteristics for EPN meet or exceed the delayed toxic effect risk criterion (40 CFR 154.7(a)(2)) for Special Review. Also, the Agency has determined that certain additional or revised label restrictions are necessary to reduce worker and environmental exposure during the period necessary to complete the Special Review. These include:

Restricted Use Classification with Corresponding
    Statement of Reason
Protective Clothing
Reentry Intervals

The Agency has also identified missing data necessary to more fully evaluate the human and environmental risks associated with the use of EPN. These data must be developed in order to maintain registrations of existing products or register any new products containing EPN. All data submitted to the Agency must comply with PR Notice 86-5. A summary of the data gaps for EPN is given in Table 2. Note that this is only a summary and that complete details can be obtained by referring to the tables in Appendix I.

The Regulatory Position and Rationale section of this Registration Standard discusses the Agency's position on each of the regulatory issues concerning EPN, and the Required Labeling section contains the specific wording changes for each of the labeling provisions necessary in order for EPN products to remain in compliance with the requirements of FIFRA.

Table 2. Summary of Data Gaps for EPN.

(Refer to the tables in Appendix 1 for detailed information regarding these requirements. Also note that all data submitted to the Agency must comply with PR Notice 86-5.)

Toxicology

Acute delayed neurotoxicity - single dose NOEL
Dermal sensitization
Chronic toxicity (two species - rodent and non-rodent)
Oncogenicity study (two species - rat and mouse preferred)
Reproductive study
Metabolism

Environmental Fate

Hydrolysis
Photodegradation, water
Photodegradation, soil
Aerobic metabolism
Anaerobic metabolism
Leaching and adsorption/desorption
Soil dissipation
Long-term soil dissipation
Rotational crop (confined)
Rotational crop (field)
Fish accumulation
Droplet size spectrum
Spray drift field evaluation

Ecological Effects

Avian reproduction study
Fish early life-stage study
Aquatic invertebrate life-cycle study
Aquatic monitoring or mesocosm study

[continued on page 15]

Table 2. Summary of Data Gaps for EPN. (continued)

Residue Chemistry

Storage stability study
Plant metabolism study
Animal metabolism study
Residue data for almonds, apples, apricots, beans (snap and lima), cherries, citrus, grapes, lettuce, nectarines, olives, peaches, pears, pecans, plums, soybeans, sugar beets (without tops), and walnuts.
Residue data and usage proposal for beets and beet greens, blackberries, boysenberries, dewberries, loganberries, pineapples, quinces, raspberries, rutabagas, spinach, strawberries, turnips and turnip greens, and youngberries. (tolerances for these items will be revoked if residue data and usage proposals are not submitted)
Processing data for residues of EPN in sugar beets, soybeans, tomatoes, citrus, prunes, grapes, apples, cottonseed, corn, and olives.
Residue data and tolerance proposals for bean vines and hay, sugar beet tops.

Special Processing Studies to provide:
- ° Residue data for cooked (microwaveing and boiling) sweet corn.
- ° Residue data on fresh unwashed tomatoes
- ° A washing study to provide residue data on lettuce

2. Summary of New Agency Positions Based on Information and Assumptions Used in the Current Assessment of Risk

a. NOEL Used

In the EPN RPAR published in 1983 (48 FR 39494) the Agency relied primarily on the NOEL of 0.1 mg/kg/day for EPN-induced depression of plasma and RBC cholinesterase levels in humans as the NOEL for delayed neurotoxicity. On that basis, the Agency calculated dietary and applicator risks posed by continued uses of EPN. The Agency concluded that adequate MOSs existed for human dietary exposure and for applicators with the exception of flaggers. The Agency used the cholinesterase-inhibition data to establish the NOEL because they were the best data available at the time.

Information received since that time on various cholinesterase-inhibiting compounds indicates an effect on blood cholinesterase is not necessarily the most sensitive indicator of toxicity for organophosphates. This means that using the effect of EPN on human blood cholinesterase may not be appropriate for determining human sensitivity to this compound, particularly for its delayed neurotoxic effect.

New information on recovery after a single large dose of EPN in hens (Huntingdon Research Centre Ltd., Report No. NSA 19(b)/86335, June 20, 1986) indicates that the spinal histopathological changes are irreversible. This finding has led the Agency to conclude that the most appropriate NOEL to use for risk assessment purposes and the most sensitive indicator of potential human toxicity for this histopathological effect is 0.01 mg/kg/day from the 90-day subchronic feeding study in hens.

Using this NOEL to calculate risk from dietary exposure to EPN, the Agency believes that the MOSs are not adequate for applicators and mixer/loaders exposed to EPN. The Agency also believes that the MOSs are not adequate for human adults and children who eat more than average amounts of corn and tomatoes during the fresh market season. Therefore, the Agency has determined that a Special Review of the chemical for the potential delayed neurotoxic effect is necessary.

b. Reentry

In the 1983 RPAR document, the Agency did not calculate potential risk to workers reentering fields treated with EPN because there were no dislodgeable residue data available on which to calculate exposure. Data received since that time have enabled the Agency to conduct an exposure and risk assessment for five crops. The resulting MOSs are apparently inadequate. Therefore, the reentry intervals must be revised as discussed below in Section IV. A. 5. (Regulatory Position and Rationale).

c. Margin of Safety Limits

In the 1983 RPAR document, the Agency considered that a MOS of 10 relative to the blood cholinesterase NOEL in the human study was adequate; any number below 10 was deemed inadequate in view of the benefits derived from the use of EPN. However, because the new recovery study shows that the spinal histopathological changes in the hen are irreversible, a MOS of at least 100 is considered necessary. The spinal histopathological changes have been shown to be the most sensitive indicator for potential human toxicity.

3. Summary of Agency Position on Other Effects

In the 1979 RPAR, the Agency identified 5 other possible adverse effects of EPN for which insufficient information existed to issue a rebuttable presumption. The following paragraphs summarize the Agency's current position on these effects.

a. Teratogenicity

Two acceptable studies in the rat and rabbit do not demonstrate teratogenic effects. These studies are described in detail in Section III. B. 5. below. The Agency has determined that EPN has not been shown to be teratogenic. No further teratology data are required by the Agency at this time.

b. Cholinergic Effects

EPN produces clinical signs of toxicity secondary to its inhibition of cholinesterase. These signs are a result of accumulation of acetylcholine in the organism and are cholinergic responses. The delayed response shortly after dosing is indicative of a secondary cholinergic response. The Agency concludes that there is no evidence that EPN has a direct effect on cholinergic receptors. However, because EPN has been shown to be acutely toxic due to inhibition of cholinesterase, the Agency is requiring a Restricted Use Classification.

c. Disorders of the Eye

The 1979 Position Document stated that one study in Japan indicated that eye disorders such as reduced vision, narrowing of the visual field, abnormal refraction and other abnormalities were observed. However, the subjects were exposed to several pesticides, not just EPN, and the amount of EPN exposure was not determined. Since that time the Agency has been unable to find evidence that EPN causes disorders of the eye, thus reaffirming its position in the original 1979 RPAR that a risk criterion for this effect has not been met or exceeded.

d. Mutagenicity

Information on mutagenic effects is detailed below in Section III. B. 7. The Agency concludes, based on all mutagenicity studies submitted and reviewed, that EPN is not mutagenic.

e. Reductions in Honeybee Populations

The Agency has reviewed data which show that EPN is highly toxic to honeybees (Atkins et al., 1975). The Agency concluded that labels of end-use products intended for foliar application must contain a bee precaution statement. Section IV. D. of this Registration Standard continues this requirement.

f. Potentiation

In the 1979 RPAR position document the Agency stated that animal studies indicated that EPN was observed to potentiate (enhance) the acute toxicity of malathion, dimethoate, and systox. The Agency requested information regarding use practices in the United States to determine whether these pesticides were actually used in combination with each other. E.I. Du Pont de Nemours responded to the RPAR and pointed out that there are no registered products which contain EPN in combination with these other pesticides and that tank mixes are not used either. Because it does not appear that these products are used in combination the Agency concludes that the risk of potentiation is not now of concern.

B. HEALTH RISK ASSESSMENT

The Agency has reviewed EPN data in the areas of acute toxicity, chronic toxicity, oncogenicity, reproductive effects, mutagenicity, environmental fate and exposure, and ecological effects. Numerous data gaps exist. The following assessment is based on available data and is subject to change when the results of the required studies are available for Agency review.

1. Acute Toxicity

Adequate data are available to fully assess the acute oral, dermal, and inhalation toxicity of technical EPN. These data indicate a high acute oral toxicity to mammals with LD_{50} values of approximately 52.8 and 13.2 mg/kg/body weight in male and female rats, respectively (E.I. du Pont de Nemours & Co., Inc., 1949); acute dermal LD_{50} values of 354 and 500 mg/kg/body weight in male and female rabbits, respectively (International Research and Development Corp., Study No. 163-495, Nov. 8, 1977); and acute inhalation LD_{50} values of 0.076 and 0.024 mg/liter (l) in male and female rats, respectively (Haskell Laboratory Report No. 32-71, Feb. 5, 1971). These values place EPN in Toxicity Category I on the basis of acute oral toxicity; Toxicity Category II on the basis of acute dermal toxicity; and Toxicity Category I on the basis of acute inhalation toxicity.

Sufficient data are also available for the Agency to conclude that technical EPN does not produce eye irritation or dermal irritation (International Research and Development Corp., Dec. 29, 1975 revised Mar. 16, 1976). Technical EPN is in Toxicity Category IV on the basis of dermal irritation.

There are no dermal sensitization studies available on technical EPN; therefore, this effect cannot be assessed. The Agency is requiring a dermal sensitization study.

The Agency has sufficient data to determine that technical EPN produces organophosphate type delayed neurotoxicity in the hen (Huntingdon Research Centre Ltd., NSA 19(a)/8646, May 9, 1986). The acute oral LD_{50} of EPN in adult hens was determined to be 171 mg/kg. A single oral dose of 175 mg/kg EPN produced organophosphate type delayed neurotoxicity. Eight of the surviving birds showed signs of delayed neurotoxicity. Neuropathological abnormalities in excess of those observed in control animals were observed in 10 of 11 EPN dosed birds.

The Agency does not have a study on which to base a NOEL for spinal histopathological changes for a single toxic dose; therefore, an acute delayed neurotoxicity study must be submitted by the registrants.

2. Subchronic Toxicity

Adequate data are available to satisfy the data requirements for subchronic oral toxicity studies in a rodent and a nonrodent species. In a subchronic rat study (Hazleton Laboratories America, Project No. 2096-111, Feb. 24, 1986), 10 animals of each sex at each dose level were dosed with EPN orally for 13-weeks at doses of 1, 5, 25 and 125 parts per million (ppm) in the diet. Ten extra animals included in the high dose group were maintained for a 4-week post-dose recovery period.

EPN-related effects were depression of cholinesterase activity (plasma NOEL 25 ppm, red blood cell (RBC) NOEL 5 ppm and brain NOEL 25 ppm); decreased growth in the females at 125 ppm; decreased erythrocyte parameters in both sexes at 125 ppm; and increased splenic pigmentation (hemosiderin) in the females at all doses.

In a subchronic dog study (Hazleton Laboratories America, Project No. 2096-121, Feb. 24, 1986), 4 animals of each sex at each dose level were dosed orally by capsule for 13-weeks at doses of 0.3, 1.0, and 3.0 mg/kg/day. During ophthalmoscopic examinations at week 13, seven of the eight animals at the 3.0 mg/kg/day dose showed EPN-induced miosis (constriction of the pupil of the eye). An EPN-related decrease in red blood cell parameters, indicative of increased destruction and/or early breakdown of red blood cells, was observed in the high dose males at treatment weeks 4, 7 and 13. The same values were depressed in females at the high dose, but there was some indication of recovery at week 13. Plasma cholinesterase activity was reduced in the 3.0 mg/kg/day group in both sexes at 4, 7 and 13 weeks and in the 1 mg/kg/day males at 4, 7 and 13 weeks ($p \leq 0.05$). RBC cholinesterase activity was decreased in the 3 mg/kg/day group in both sexes at 4, 7 and 13 weeks ($p \leq 0.05$). Brain cholinesterase activity was significantly decreased at 3.0 mg/kg/day in both sexes ($p \leq 0.05$). The authors of the study stated "The most remarkable histopathological finding in the treated animals was pancreatic acinar cell atrophy present in two Group 4 males."

Sufficient data are available to the Agency to satisfy the requirement for a 21-day dermal study in rats (Hazleton Laboratories America, Project No. 209-6120, Oct. 29, 1985). In this study rats were randomly assigned to the following groups.

Group	No. of Animals Males	No. of Animals Females	EPN Technical Dosage Levels (mg/kg/day)[a] Males	EPN Technical Dosage Levels (mg/kg/day)[a] Females
1	5	5	0	0
2	5	5	2.5	0.5
3	5	5	7.5	1.5
4	5	5	25.0	5.0
5	5	5	75.0	15.0

[a] All applications were given in a dosage volume of 1.0 ml/kg in acetone solvent.

EPN applied dermally for 21-days produced signs typical of organophosphate toxicity at the highest doses (75 mg/kg/day for the males and 15 mg/kg/day for the females). A NOEL for the most sensitive effect, cholinesterase inhibition in plasma and RBC, was demonstrated at 0.5 mg/kg/day.

No data are available to the Agency on the 90-day dermal toxicity of EPN. However, based on the expected exposure, the Agency is not requiring a 90-day dermal toxicity study.

The Agency has adequate data to characterize the 13-week inhalation toxicity of EPN in rats (Hazleton Laboratories Europe Ltd., Report No. 5160-306/13, July 1986). In this study ten rats per sex per dose were tested at 0.093, 0.731 and 7.859 micrograms per liter (ug/l) for male rats and 0.0094, 0.093 and 0.731 ug/L for female rats. The only effect observed was depressed RBC cholinesterase activity in the high dose males.

Sufficient data are available to the Agency to show that EPN produces organophosphate type delayed neurotoxicity in two 90-day oral studies in the chicken.

In the first study by Abu-Donia and Graham (Toxicology and Applied Pharmacology 45:685-700; 1978) hens (6 per dose) were dosed at 0.01, 0.1, 0.5, 1.0, 2.5 and 5.0 mg/kg/day by capsule. Signs of neurotoxicity were observed at doses of 0.1 to 5.0 mg/kg/day with a NOEL of 0.01 mg/kg/day. Histopathological evidence of neurotoxicity (neuronal degeneration) were detected in the spinal cord at doses of 1.0 mg/kg/day and higher. A dose of 0.5 mg/kg/day was a NOEL for this effect.

In the second study (Huntingdon Research Centre, DAS 2181637, Mar. 3, 1982) hens (20 per dose) were dosed at 0.01, 0.1, 0.5, 1.0, 2.5 and 5.0 mg/kg/day by capsule. Signs of neurotoxicity were observed at doses of 2.5 and 5.0 mg/kg/day with a NOEL of 1.0 mg/kg/day. Histopathological evidence of neurotoxicity (neuronal degeneration) was detected in the spinal cord at doses of 0.1 mg/kg/day and higher. A dose of 0.01 was a NOEL for this effect. This study is discussed in detail below in Section III. B. 10.

After reviewing all of the subchronic toxicity studies, the Agency has determined that a dose of 0.01 mg/kg/day for histopathological effects is the most sensitive NOEL on which to base a human risk assessment.

3. Chronic Toxicity

No data are available to the Agency on the chronic oral toxicity of technical EPN in rodent and nonrodent sepcies. The Agency is requiring a two-year feeding study in the rat and a one-year feeding study in the dog.

4. Oncogenicity

No data are available for the Agency to evaluate the oncogenic potential of technical EPN. The Agency is requiring life-time feeding studies in the rat and the mouse.

5. Teratogenicity

Sufficient data are available in the rat and the rabbit to satisfy the requirements for teratology studies of EPN.

In a teratology study in the rat (Hazleton Laboratories America, Report No. 2096-115, Sept. 4, 1986), 25 females per dose were dosed at 0.3, 0.6, 1.2 and 2.4 mg/kg/day during days 6 - 15 of gestation. Clinical signs of EPN toxicity were observed in the high dose females and consisted of tremors, prostration, urine stains, hunched appearance, bloody crust on the eye lids and nose, rhinorrhea and lacrimation. No fetal toxicity was observed at the highest dose tested.

In a teratology study in the rabbit (Hazleton Laboratories America, Report No. 2096-116, Sept. 4, 1986), 15 females per dose were dosed at 1, 3, 6 and 9 mg/kg/day during days 7 - 19 of gestation. Twelve females died or were sacrificed due to morbidity at 9 mg/kg/day. Signs of toxicity including languidness, prostration and salivation were observed in the does sacrificed and in the survivors. Two 6 mg/kg/day females were found dead. No signs of toxicity were observed in these females. The only possible compound-related effect on the fetuses was significantly lower mean fetal body weights in the females at 6 and 9 mg/kg/day.

The Agency has determined, based on these two studies, that EPN has not been shown to be teratogenic.

6. Reproduction

No data are available for the Agency to evaluate the effects of EPN on reproduction. The Agency is requiring a reproduction study in the rat.

7. Mutagenicity

The Agency has sufficient data to evaluate the mutagenic potential of EPN. EPN technical was weakly mutagenic in a single replicate of one of the tests utilized. Based on all mutagenicity tests submitted, it is concluded that EPN is not mutagenic.

Two gene mutations studies were available. The first study (Microtest Research Ltd., Study No. NCJ1/S/AF4/SA3, Oct. 22, 1985) was performed to determine the ability of technical EPN to induce mutation in four histidine-requiring strains of Salmonella typhimurium. EPN was not mutagenic in Salmonella typhimurium strains TA98, TA100, TA1535 or TA1537 at doses up to 2500 ug/plate either with or without metabolic activation.

The second study (Microtest Research Ltd., Study No. NCJ1/MLK/KF20/ML3, Apr. 7, 1986) was performed to determine the ability of technical EPN to induce mutation to 6-thioguanine resistance in mouse lymphoma L5178Y cells. EPN was weakly mutagenic in one of two replicates, in mouse lymphoma L5178Y cells in vitro in the presence of liver S-9 fraction. Mutagenic activity was approximately 1/1000 to 1/500 of the positive control. Because of the ambiguity and weakness of the results obtained, the study cannot be considered definitive in and of itself.

Two chromosomal aberration studies were available. The first study (Microtest Research Ltd., Study No. NCJ1/CHO/KF17/CH3, Oct. 22, 1985) was performed to evaluate the chromosome damaging potential of EPN technical by its effects on cultured Chinese hamster ovary (CHO) cells using an in vitro cytogenetic assay. EPN technical, at doses up to 5000 micrograms per milliliter (ug/ml), did not cause an increase in chromosomal aberrations when tested on cultured Chinese hamster ovary cells either with or without metabolic activation with rat liver S-9 fraction.

The second study (Microtest Research Ltd., Study No. NCJ1/MNT/KF19/MN1, Oct. 22, 1985) was performed to evaluate the potential of technical EPN to induce micronuclei in the bone marrow of treated mice. EPN did not induce micronuclei in the bone marrow of mice treated with a single oral dose of 30 mg/kg.

One unscheduled DNA synthesis study (Microtest Research Ltd., Study No. NCJ1/He/KF16/HE2, Oct. 23, 1985) was performed to determine the ability of technical EPN to induce unscheduled DNA synthesis in HeLa Cells. EPN, at doses up to 500 ug/ml, does not induce unscheduled DNA synthesis in HeLa cells either with or without metabolic activation.

8. Metabolism

The Agency has data to partially satisfy the requirement for a metabolism study of EPN in rats.

In these studies (Hazleton Laboratories Europe, Report No. 4958-306/14, April 1986) EPN was administered orally, by gavage, as a solution in corn oil to the dose groups. Noted below are the findings of the excretion study and pharmacokinetic study:

Excretion study:

Group	Sex	Number	Dose EPN Unlabeled EPN mg/kg/day	Dose EPN Labeled ^{14}C EPN* mg/kg/day
A	Males	5		0.8
	Females	5		0.3
B	Males	5	0.8 (14 days)	0.8
	Females	5	0.3 (14 days)	0.3
C	Males	5		30.0
	Females	5		15.0

*Labeled EPN is EPN that has a radioactive isotope added in order to trace its course and behavior in living organisms.

In both sexes labeled ^{14}C EPN was excreted by urine and feces over a period of 5 to 6 days for the low dose and 7 days for the high dose. Excretion appears to be biphasic, with the majority of the labeled EPN excreted in 48 hours for both low and high doses. Pretreatment with unlabled EPN for 14 days increased the relative portion of labeled EPN excreted in the urine and during the first 12 hours in both sexes. This also reduced the total excretion time to four days, indicating induction of metabolizing enzymes. Because different doses were used for each sex in each dose regimen, it was impossible to compare the relative excretion by sex. As there is approximately a seven fold difference in acute toxicity by sex (it is more toxic in females), this is a critical deficiency in the study. The male portion of the study must be repeated using the doses that were used for the females.

The effect of the pretreatment dose regimen on the portion of the labeled EPN excreted in the urine in both males and females also indicates that biliary excretion may be responsible for all or part of the fecal excretion observed. An experimental evaluation of this possibility is needed.

Analysis of urine and feces showed the existence of several possible metabolites. However, these were not identified. Further work must be performed to identify the metabolites.

Tissue analysis showed relatively higher concentrations of radioactivity in kidney, lung and liver. There appear to be some dose-related differences in this residue. Due to the use of different doses for each sex, it is impossible to determine if there are sex-related differences. The quantities remaining in these organs do not appear to be toxicologically significant.

Pharmacokinetic study:

Group	Sex	Number	Dose EPN* Labeled ^{14}C EPN mg/kg/day
A	Males	5	0.8
	Females	5	0.3
C	Males	5	30.0
	Females	5	15.0

*Labeled EPN is EPN that has a radioactive isotope added in order to trace its course and behavior in living organisms. Only labeled EPN was used in this kinetics study.

This kinetics study showed peak blood concentrations 12 hours after dosing for both doses and sexes. The clearance curve appears to be biphasic. Again, the use of different doses in each sex makes sex-related comparisons impossible. This is a scientific deficiency, but since this study is not required it is not considered a regulatory deficiency.

9. Neurotoxicity Recovery Study in Hens

In order to satisfy an Agency requirement, a study was performed to determine the ability of hens to recover from a single oral dose of EPN (Huntingdon Research Centre Ltd., Report No. NSA 19(b)/86335, June 20, 1986). A dose of 175 mg/kg in atropine-protected hens was selected as capable of producing signs of organophosphate delayed neurotoxicity (ataxia) in approximately half of the treated hens without producing excessive lethality.

A total of 80 hens were protected with atropine against acute toxicity and given a single oral dose of 175 mg/kg EPN. All treated hens and 10 untreated controls were observed and graded for ataxia. Groups of five treated hens were sacrificed for histopathology of selected parts of the central nervous system (CNS) and sciatic nerve at intervals for up to 90 days post dose. Five controls were sacrificed at 45 days and 5 at 90 days.

A total of 20 hens showed delayed ataxia during the study. Some of the birds which showed ataxia, and were retained for sufficient time, showed improvement and recovery. Five hens, with mild class 1 or 2 ataxia recovered fully and 7 hens with more severe ataxia showed some measure of improvement in gait. Histopathology showed mild damage to the sciatic nerve in all 20 hens and complete nerve recovery with time. After the 40-day sacrifice all samples were normal. However, relatively severe damage (grade III and IV) was observed in the spinal cord and recovery was relatively minor. There was no correlation between the severity of the histopathology of the spinal cord and the occurance of signs of toxicity. All 48 hens sacrificed at 40 days, and later, showed grade III and/or IV histopathological damage in the cord, yet only 12 of these hens showed signs of neurotoxicity (ataxia). By this time the sciatic nerves and branches were normal. There was nothing in the spinal cord histopathology to distinguish any single hen showing signs of neurotoxicity from the hens which did not show neurotoxicity.

A reexamination of the histology slides from the 20 hens could not distinguish between the hens hens which showed ataxia and those which did not.

10. Toxicological Issues Associated with Delayed Neurotoxicity

Organophosphate delayed neurotoxicity was first observed in man during the prohibition era in the United States. A drink called Jamaica Ginger was contaminated with tri-o-cresyl phosphate (TOCP), a component of the organic solvent used to prepare ginger extract. Humans exposed to the contaminated ginger extract developed a paralysis of the legs and arms. The severity of the paralysis varied with the victim's exposure to the contaminant. Animal studies identified TOCP as the toxic agent and characterized this paralysis syndrome which is now called Organophosphate Type Delayed Neurotoxicity. Subsequently, this syndrome was observed following accidental human exposure to the pesticide leptophos and the experimental compound mipafox, both of which are organophosphate inhibitors of cholinesterase.

Organophosphate type delayed neurotoxicity is characterized as follows: 1) A delay in the order of 10 - 14 days between a single effective dose and the appearance of clinical and histopathological signs; 2) The appearance of the delayed effect well after recovery from the acute toxicity of the compound; 3) No apparent relationship between the compound's ability to inhibit blood cholinesterase and its ability to produce the delayed effect; 4) The appearance of abnormalities of gait which may proceed to complete paralysis and are generally irreversible; 5) The destruction of nerve axons in the sciatic nerve and the spinal cord and the subsequent disappearance of the myelin sheath which surrounded the lost axons; and 6) The delayed toxic effect can also be produced by daily administration of doses which individually will not produce the acute toxic response, i.e., the delayed toxicity is cumulative.

Animal studies with TOCP showed that the toxic syndrome could not be produced in rats and mice and was produced only with inconsistent or atypical results in dogs and cats. The syndrome has been demonstrated in bovine and primate species. The chicken has been shown to consistently demonstrate the syndrome with the three compounds that are active in man and, for practical purposes, has become the species of choice for detecting this toxic effect.

Several studies with EPN in the chicken have demonstrated the organophosphate delayed neurotoxic syndrome. The studies reviewed in this standard verify the previous reports. They characterize more precisely the dose and time relationship of the neurotoxic effect and provide information on the ability of the experimental animal to recover from the effect.

In the acute oral study (Huntingdon Research Centre Ltd., NSA 19(a)/8646, May 9, 1986), a nominal LD_{50} of 175 mg/kg EPN produced signs of delayed neurotoxicity in 8 of 14 hens which survived the acute lethality. Histopathology characteristics of the syndrome were observed in the spinal cord and sciatic nerve.

Two 90-day oral dosing studies summarized above in Section III. B. 2., were performed in hens and used the same doses. These studies provided contradictory evidence as to a NOEL. The doses used were 0.01, 0.1, 0.5, 1.0, 2.5 and 5.0 mg/kg/day by capsule.

In the first study Abou-Donia (Toxicology and Applied Pharmacology 45:685-700; 1978) reported the NOEL for neurotoxic signs (ataxia) as 0.01 mg/kg/day. The histopathologically determined NOEL was reported as 0.5 mg/kg/day.

In the second study Huntingdon Research Centre (DAS 2181637, Mar. 3, 1982) reported the NOEL for clinical neurotoxic signs (ataxia) as 1.0 mg/kg/day. The histopathologically determined NOEL was reported as 0.5 mg/kg/day. However, an evaluation of the report of this study by the Agency concluded that histopathological changes of the spinal cord were observed at doses as low as 0.1 mg/kg/day and that a dose of 0.01 mg/kg/day was a NOEL. This conclusion was based on a shift in the relative number of grade I and II slides reported in the hens dosed at 0.1 and 0.5 mg/kg/day compared with the untreated controls. Although both grades are considered within the range of normality, the dosed hens showed relatively more grade II slides than the controls. Grade I has been described as showing no abnormalities and grade II as, "Disruption or fragmentation of occasional axons. Myelin abnormalities were rare. In general on any slide prepared from the spinal cord (two longitudinal and one transverse sections), between one and four degenerate/ altered axons were detected. On a slide of peripheral nerve one or two degenerate axons were included in this grade." The ratings of these histopathological changes in the spinal cord of hens treated for 90 days with EPN at various doses is shown in Table 3.

The most sensitive NOEL of 0.01 mg/kg/day for histopathological changes in the spinal cord was used as a basis for the risk assessments discussed below in Section 11.

The recovery study discussed above in Section III. B. 9. (Huntingdon Research Centre Ltd., Report No. NSA 19(b)/86335, Jun. 20, 1986) has provided new information on the long-term effects of a single dose of EPN on gait and on histopathology of the nervous system. Humans and experimental animals poisoned by compounds producing delayed neurotoxicity have displayed a measure of 'recovery' in locomotor activity with time. It is not known if this recovery is due to reversal of nerve damage, to compensation such as occurs following stroke or to some combination of both. The recovery study was designed to provide experimental information on this 'recovery': was it real, and if so what was the possible mechanism.

Of the hens which showed delayed ataxia during the study, five hens with a mild class 1 or 2 ataxia recovered fully and seven hens with more severe ataxia showed some measure of improvement in gait. Histopathology showed mild damage to the sciatic nerve and complete nerve recovery with time; after 40-day sacrifice all samples were normal. In the spinal cord recovery was relatively minor from a generally more severe damage. The Agency considers that this cellular destruction in the spinal cord is serious because these cells are never replaced; the damage is permanent.

An additional critical and unexpected observation was the lack of correlation between the severity of the histopathology and the occurrence of clinical signs of toxicity (ataxia). All 48 hens sacrificed at 40 days, and later, showed grade III and/or IV damage in the cord yet only 12 of these hens showed ataxia. By the time of sacrifice the sciatic nerves and branches were normal. There was nothing in the histopathology to distinguish any single hen showing signs of ataxia from the hens which did not show ataxia.

Table 3 - Ratings of Histopathological Changes in the Spinal Cord of Hens Treated For 90 Days With EPN

	GRADE[1]									
	I		II		III		IV		V	
DOSE	#	%	#	%	#	%	#	%	#	%
0.00	30	75	10	25	0	0	0	0	0	0
0.00	28	70	11	28	1	3	0	0	0	0
0.01	39	89	5	11	0	0	0	0	0	0
0.10	23	58	17	43	0	0	0	0	0	0
0.50	29	66	15	34	0	0	0	0	0	0
1.00	13	41	14	44	5	16	0	0	0	0
2.5	26	54	13	30	3	7	2	5	0	0
5.0	11	25	10	25	12	27	9	20	2	5
10.0	11	17	4	6	16	25	22	34	11	17

[1] The gradings of histopathological changes represent an increase in severity from Grade I to Grade V.

This situation has never been reported previously, most likely because this type of study, with periodic serial sacrifices occurring after 40 and through 90 days following a single dose of a delayed neurotoxin, had never previously been performed. Acute studies containing a recovery phase usually go only 30 days post dose and have no interim sacrifices.

The 90-day oral dosing study by Huntingdon Laboratories (DAS 2181637, Mar. 3, 1982) included a 90-day recovery period. The study also used three doses of TOCP as a positive control. Histopathological signs of nerve damage were clearly seen in the spinal cord for both compounds but, while present, were minimal in the peripheral nerve (sciatic and branches). In the spinal cord, effective doses of TOCP showed possible deterioration and no evidence of recovery. Effective doses of EPN were equivocal in relation to recovery; there is some indication of a dose-related recovery in the groups given 0.1 through 0.5 mg/kg/day, but there is also an indication of deterioration at 0.01 mg/kg/day. In the peripheral nerve, recovery from both compounds could be considered complete at 90 days post dose since the treated hens could not be distinguished from the controls.

11. Risk Assessments for Delayed Neurotoxicity

To assess the risks to the public who consume EPN treated food commodities and to workers involved with application of EPN, the Agency estimated dietary and worker exposures and compared these to the NOEL for histopathological effects of delayed neurotoxicity. These comparisons are expressed as margins of safety (MOSs) and the assessments are presented below. The Agency used the NOEL of 0.01 mg/kg/day for histopathological effects in the spinal cord. derived from the Huntingdon Laboratories subchronic feeding study in hens (DAS 2181637, Mar. 3, 1982). Even if the Agency used the reported, histopathologically determined NOEL of 0.5 mg/kg/day, the risk concerns expressed below would remain unchanged.

Dietary Risk Assessment

Dietary exposure occurs from consumption of food crops treated with EPN. The Agency assessed dietary exposure and risk under three scenarios: (1) EPN residues on food commodities at the established tolerance levels and assuming 100% of the crop acreage is treated, (2) for five crops for which the Agency has actual crop residue data; EPN residues are at levels suggested by these data, and (3) scenario 2, except assuming the appropriate percent of crop treated for each crop.

In calculating the Maximum Permissible Intake (MPI) (for comparison to dietary exposure), the following assumptions were used: the NOEL of 0.01 mg/kg/day, an average body weight of 60 kg, a daily diet of 1.5 kg, and a safety factor of 1,000. This level of safety factor (or uncertainty factor) is considered appropriate for subchronic studies. The Acceptable

Daily Intake (ADI) was obtained by multiplying the NOEL of 0.01 mg/kg/day by the safety factor of 1000 to yield 0.00001 mg/kg/day. Assuming a person weighs 60 kg, the MPI was calculated to be 0.0006 mg/day (0.00001 X 60).

Table 4 (Scenario 1) shows the percentages of the MPI for EPN as a function of consumed residues based on an individual consuming commodities containing EPN at tolerance levels, at the given food factor levels, and consuming 1.5 kg of food per day. (The food factors represent the percent of the commodity eaten by a person in his/her diet each day). The total percentage of the MPI from all crops is 164,000%. A total percentage of the MPI of up to 100% is generally a regulatory standard of acceptability.

The Agency believes that the resultant figure of 164,000% MPI is not a realistic estimate because of the worst case assumptions used in the calculation, such as that 100% of the crop acreage is treated with EPN and that all commodities are at tolerance level. However, even considering these exaggerated assumptions the Agency is still concerned about the dietary exposure.

The Agency has only a limited amount of data at this time for more realistic estimates of EPN residue levels on the commodities and the percentages of the crops' acreages that are treated with EPN. However, for five crops (soybeans, dry beans, tomatoes, corn, and cotton) the Agency has these data. Dietary exposure to EPN residues from these five crops and the percentage of the MPI were assessed. These assessments, based on maximum observed residues based on field studies and percentage of crop treated, were compared to assessments based on these five crops at the tolerance levels and 100% of the crop acreages treated. These assessments are presented in Table 5. Based on using tolerance levels and 100% of the acreage treated, the dietary exposure from these five crops results in 56,000% of the MPI. However, when the assessment is corrected for estimates of highest expected residue levels and percent acreage treated, the percentage of the MPI for these five crops falls to 120%.

In another dietary assessment of EPN residues, the Agency chose three commodities (cooked corn, corn on the cob, and fresh whole tomatoes) to demonstrate the chronic dietary exposure and the MOSs for the spinal histopathological effect as calculated using the Tolerance Assessment System (TAS). (The TAS is a computer-based tool which estimates dietary exposure to a pesticide and then compares that estimate to a previously determined acceptable daily intake. The TAS data files are composed of food comsumption estimates (based on dietary intake records for 30,770 individuals), toxicology data on the chemical, and residue concentrations.) These MOSs

Table 4 - Dietary Exposure and Its Percent of the Maximum Permissible Intake

Crop	Tolerance (ppm)	Food Factor[1] (%)	mg/day[2] (1.5 kg diet)	Percent MPI
Almonds	0.500	0.03	0.00023	38
Apples	3.000	2.53	0.11385	18,975
Apricots	3.000	0.11	0.00506	843
Beans	3.000	2.04	0.09180	15,300
Beets	3.000	0.17	0.00782	1,303
Beet greens	3.000	0.03	0.00135	225
Blackberries	3.000	0.03	0.00135	225
Boysenberries	3.000	0.03	0.00135	225
Cherries	3.000	0.10	0.00460	767
Citrus fruits	3.000	3.81	0.17154	28,590
Corn, all types	3.000	2.51	0.11295	18,825
Cotton seed (oil)	0.500	0.15	0.00112	186
Dewberries	3.000	0.03	0.00135	225
Grapes, incl raisins	3.000	0.49	0.02207	3,678
Lettuce	3.000	1.31	0.05887	9,811
Loganberries	3.000	0.03	0.00135	225
Nectarines	3.000	0.03	0.00135	225
Olives	3.000	0.06	0.00276	460
Peaches	3.000	0.90	0.04047	6,745
Pears	3.000	0.26	0.01150	1,917
Pecans	0.500	0.03	0.00023	38
Pinneapple	3.000	0.30	0.01334	2,223
Plums, incl prunes	3.000	0.13	0.00598	997
Quinces	3.000	0.03	0.00135	225
Raspberries	3.000	0.03	0.00135	225
Rutabagas	3.000	0.03	0.00135	225
Soybeans	0.050	0.92	0.00069	115
Spinach	3.000	0.05	0.00230	383
Strawberries	3.000	0.18	0.00828	1,380
Sugar, cane & beet	3.000	3.64	0.16372	27,286
Tomatoes	3.000	2.87	0.12937	21,562
Turnips	3.000	0.05	0.00230	383
Turnip greens	3.000	0.03	0.00135	225
Walnuts	0.500	0.03	0.00023	38
Youngberries	3.000	0.03	0.00135	225
				Total = 164,317

Theoretical Maximum Residue Contribution (TMRC) is 0.9856 mg/kg/day for a 60 kg person.

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[1] In the calculation of daily dietary exposure, the Agency used appropriate food factors, i.e., the percent of that commodity eaten by the general population in one day. For example, almonds represent 0.03% of a person's daily dietary intake.

[2] The dietary intake was calculated assuming that 100% of each crop was treated with EPN; however, useage date indicate that about 7% of corn is treated, 3% of cotton is treated and less than 1% of each of the remaining crops are treated

Table 5 - Dietary Exposure From Five Crops Based on Tolerance Levels and 100% Crop Treated

Crop	Tolerance (ppm)	Food Factor(%)	Dietary Expo. (mg/day, 1.5 kg diet)	% of MPI
Soybean Oil	0.05	0.92	0.00069	115
Dry Beans	3.0	2.04	0.09180	15,300
Tomatoes	3.0	2.87	0.12937	21,562
Sweet Corn	3.0	2.51	0.11295	18,825
Cottonseed Oil	0.5	0.15	0.00112	186
TOTALS			0.33593	55,988 %

Dietary Exposure From Five Crops Based on Actual Residues and Percent Crop Treated

Crop	Highest Expect. Res. (ppm)	Food Factor(%)	% Crop Treated	Dietary Expo. (mg/day, 1.5 kg diet)	% of MPI
Soybean Oil	0.3	0.92	<1	0.0000414	6.9
Dry Beans	0.06	2.04	<1	0.0000183	3.0
Tomatoes	0.30	2.87	<1	0.0001291	21.5
Sweet Corn	0.13	2.51	6	0.0002935	48.9
Cottonseed Oil	3.5	0.15	3	0.0002362	39.4
TOTALS				0.0006915	119.7

are based on actual residues in these commodities and different amounts of consumption (average, 95th, and 99th percentile) of each commodity on a daily basis. Table 6 presents the exposure and MOS values for the U.S. population and for children. The MOSs are low for EPN exposure for adults and children who eat more than average amounts of corn and tomatoes during the fresh market season.

Specifically, for fresh cooked corn the MOSs for the general population range from 50 to 500 and for children from 25 to 200 depending upon the amount of daily consumption and the children's ages. However, for these population groups the MOSs associated with mean consumption values are between 200 and 500. The MOSs for consumption of 1 or 2 ears of corn on the cob are lower, varying from 39 to 77 for the general population and 13 to 26 for children. Finally, for fresh whole tomatoes, the MOSs for the general population range from 25 to 125, for adult males from 25 to 143, for adult females from 25 to 111, and for children from 25 to 143, depending upon the daily consumption of tomatoes. For these population groups, the MOSs based on mean consumption levels are between 111 and 143. The MOSs for these populations would decrease proportionally if corn and tomatoes were eaten in large amounts on the same day.

Non-dietary Risk Assessments (application and reentry)

Applicators and mixer/loaders are exposed to EPN during their work activities. Field workers are also exposed when entering areas treated with EPN. Typical activities of field workers include weeding and scouting.

The NOEL used was 0.01 mg/kg/day for spinal histopathological effects seen in the Huntingdon Laboratories 90-day oral feeding study in hens (DAS 2181637, Mar. 3, 1982) which assessed the effects from subchronic exposure to EPN. However, applicators, mixer/loaders, and reentry workers are primarily acutely exposed; they are not subjected to subchronic exposures over 90 days. The Agency used this study to calculate a NOEL because the study represented the best data available for human risk assessment purposes. The Agency is requesting an acute delayed neurotoxicity study to determine a NOEL for spinal histopathological effects from a single acute exposure to EPN. When this study is received and evaluated by the Agency, a new NOEL will be determined and a new risk assessment for acute exposure to humans will be calculated.

Based on average exposure values from surrogate pesticide studies, in which mixer/loaders wore gloves and typical work clothing, and applicators only wore typical work clothing, MOSs were calculated for work activities for cotton, soybeans, and field corn. MOSs for mixers/loaders for cotton, soybeans,

Table 6 - Tolerance Assessment System Analyses for Dietary Exposure and Margins of Safety Calculations

1. Fresh Cooked Corn, including fresh, corn on the cob, canned and frozen, containing 0.1 ppm EPN with no reduction of residues from cooking.

	Fresh Cooked Corn Consumption		
	Mean	95th percentile	99th percentile
	mg EPN/kg bw/d		
U.S. Population	0.00002	0.0001	0.0002
(MOS)	(500)	(100)	(50)
Children 1-6yr	0.00005	0.0002	0.0004
(MOS)	(200)	(50)	(25)
Children 7-12yr	0.00004	0.0002	0.0003
(MOS)	(250)	(50)	(33)

2. Corn on the Cob only, containing 77 gm/ear, 0.1 ppm EPN, and no reduction of residues from cooking. TAS does not single out corn on the cob but includes it with fresh corn. It is unique because (1) it is frequently consumed at relatively large quantities and/or for many consecutive days during the fresh market season, (2) it does not undergo the processing of canned or frozen corn, and (3) therefore the TAS analysis may be an underestimation of exposure.

	Corn on the Cob Consumption	
	1 Ear	2 Ears
	mg EPN/kg bw/d	
U.S. Population	0.00013	0.00026
(MOS)	(77)	(39)
Children	0.00039	0.00078
(MOS)	(26)	(13)

3. Fresh Whole Tomatoes containing 0.3 ppm EPN. During the fresh market season an individual may eat relatively large quantities and/or for many consecutive days.

	Tomato Consumption	
	Mean	95th percentile
	mg EPN/kg bw/d	
U.S. Population	0.00008	0.0003-0.0004
(MOS)	(125)	(33-25)
Males 20+	0.00007	0.0003-0.0004
(MOS)	(143)	(33-25)
Females 20+	0.00009	0.0004
(MOS)	(111)	(25)
Children 1-12 yr	0.00007	0.0003-0.0004
(MOS)	(143)	(33-25)

and field corn ranged from 0.003 for cotton to 0.5 for field corn. The daily MOS for applicators for these crops ranged from 0.05 for cotton to 1.4 for field corn (Table 7). In the absence of a dermal absorption study dermal absorption was assumed to be 31% based on a comparison of oral and dermal LD_{50} values, the best data on the subject currently available. The MOS is calculated on a daily basis because it is an acute exposure scenario.

The MOSs for field workers not wearing protective clothing were calculated for five crops (soybeans, cotton, corn, pecans, and citrus) based on dislodgeable residue dissipation data for EPN (Table 8). MOSs for one hour exposure were under 100 for all crops even several days after application. For example, for cotton the MOS is 30 for 7 days after application and did not exceed 100 until 8-14 days after application. For soybeans, corn, and pecans the MOSs are 30 after 2 days, and did not exceed 100 until 2 - 5 days after application. For citrus the MOS is 30 even at 35 days after application. Currently the Federally established reentry interval is 24 hours (40 CFR 170.3 (b)(2)).

C. ENVIRONMENTAL PROFILE

1. Ecological Effects.

Existing data are adequate to show that EPN is highly toxic to honey bees (Atkins et al., 1975). The LC_{50} was 0.245 micrograms (ug) per bee (highly toxic). As such, labels of end-use EPN products intended for foliar application must contain a bee precaution statement.

Existing data are adequate to show that technical EPN is very highly toxic to freshwater fish species, freshwater invertebrates, and estuarine/marine organisms. Short term fish bioassays with technical EPN show 96-hour LC_{50} values for rainbow and bluegill to be 80 and 190 ug/l, respectively (Union Carbide, 1976). Short term freshwater invertebrate acute studies with technical EPN show 48-hour LC_{50} values for Daphnia magna to be 0.32 ug/l (Union Carbide, 1976) and 36.0 ug/l for Gammarus lacustris (Sanders, 1969). Short term marine invertebrate studies of EPN show 96-hour LC_{50} values ranging from 4.6 ug/l for Penaeus Stylirostris to 13 ug/l for Mysidopsis bahia (U.S. EPA, 1981). The 96-hour LC_{50} values ranged from 37 ug/l for spot to 140 ug/l for sheepshead in a short term marine fish study of EPN (U.S. EPA, 1981). Eastern oyster larvae with a 48-hour EC_{50} value of 2200 ug/l were much less sensitive than either the fish or invertebrate species tested (U.S. EPA, 1981).

Two EPN formulated products, Budmor 42 (containing 20.94% EPN, 41.86% methyl parathion and 26.67% xylene) and a

Table 7 - Average Applicator Exposure and MOS to EPN[1]

Crop	Exposure Type[2]	Total Exposure mg/kg/day	Days Exposed	MOS[3] (daily)
Cotton	Aerial			
	Loading closed	0.3	2	0.1
	open	12	2	0.003
	Application	0.04	2	0.7
	Ground			
	Loading	1.5	7	0.02
	Application	0.6	7	0.05
	Combined	2.1	7	0.01
Soybeans	Aerial			
	Loading closed	0.1	2	0.3
	open	4.1	2	0.007
	Application	0.03	2	1.00
	Ground			
	Loading	1.0	2	0.03
	Application	0.3	2	0.10
	Combined	1.3	2	0.02
Field Corn	Aerial			
	Loading closed	0.07	1	0.5
	open	2.9	1	0.01
	Application	0.02	1	1.4

[1] Adapted from R. Zendzian. Internal memorandum entitled "EPN, Risk Assessment for Organophosphate Delayed Neurotoxicity, Applicator, Reentry and Dietary" Dated February 6, 1987.

[2] Based on average exposure values from surrogate pesticide studies, mixers/ loaders wearing gloves and normal work clothes, and applicators wearing only normal work clothes. Total exposure estimates amount of EPN reaching the skin, not absorbed dose.

[3] MOS calculation includes an assumed dermal absorption rate of 31%.

Table 8 - Theoretical Risk to Scouts and Field Workers From Exposure to Dislodgeable Residues after Treatment of Crops with EPN[1]

Crop	Exposed Population	Days after Application	Exposure[2] (mg/kg/hr)	MOS/hr Exposure [3] [4]
COTTON	Scouts	0	0.065	0.55
		1	0.029	1.00
		2	0.015	1.98
		5	0.006	5.00
		7	0.003	30.00
		14	0.0003	300.00
SOYBEANS	Scouts	0	0.004	7.50
		1	0.003	10.50
		2	0.001	30.00
		5	0.0001	300.00
		7	0.00005	600.00
CORN	Field Workers	0	0.01	3.00
		1	0.006	5.00
		2	0.003	10.00
		5	0.0003	100.00
		7	0.0002	150.00
		14	0.0001	300.00
PECANS	Scouts	0	0.01	3.00
		1	0.002	15.00
		2	0.001	30.00
		5	0.0003	100.00
		7	0.0002	150.00
		14	0.0001	300.00
		21	0.0001	300.00
CITRUS[5]	Field Workers	0	0.179	0.20
		1	0.097	0.30
		2	0.079	0.40
		5	0.064	0.50
		7	0.041	0.70
		14	0.023	1.30
		21	0.012	2.50
		28	0.010	3.00
		35	0.001	30.00

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[1] Adapted from R. Zendzian. Internal memorandum entitled "EPN, Risk Assessment for Organophosphate Delayed Neurotoxicity, Applicator, Reentry and Dietary" Dated February 6, 1987.

[2] Assumes 60 kg body weight

[3] Assumes 31 percent dermal absorption based on a comparison of LD_{50}s of EPN by the oral and dermal route.

[4] The NOEL is 0.01 mg/kg/day based on the 90 day feeding study in hens showing histopathological effects in the spinal cord. The Agency will recalculate this NOEL upon receipt and evaluation of the required acute delayed neurotoxicity study.

[5] Data on use of EPN on citrus gathered by the Agency indicate that EPN is not used on citrus in the United States. The exposures and MOSs are presented here to show what the theoretical risks would be if EPN were used on citrus, since it remains a currently registered use.

wettable powder (containing 25% EPN) were tested in warmwater fish and found to be highly toxic. The 96-hour LC_{50} for bluegill exposed to Budmor 42 is 650 ug/l (001000091). The 96-hour LC_{50} for fathead exposed to 25% wettable powder is 200 ug/l (Henderson et al., 1959).

Since mosquito larvicide uses of EPN have been cancelled as a result of the RPAR, contamination of water from the remaining uses of EPN is most likely to occur from runoff. Projected residues of EPN in water resulting from runoff cannot be estimated by modeling, since chemical parameters necessary for modeling are not available. However, predicting residues in water from runoff without modeling, based on use rates ranging from 0.25 to 1.0 lb ai/A, results in concentrations of approximately 2.0 to 9.0 ug/l. Predicting residues in water from runoff after application to corn at application rates of 0.25 to 0 5 lb ai/A results in concentrations of approximately 6.0 to 12 ug/l.

The LC_{50} for fish is 80 ug/l and for aquatic invertebrates is 0.32 ug/l. Comparison of these fish and aquatic invertebrate LC_{50}s to the above estimated residue levels of 2.0 to 12.0 ug/l suggests that non-target aquatic invertebrates indigenous to small ponds could be exposed to acutely toxic concentrations of EPN. The Agency is requesting actual and simulated field testing to assess more specifically potential adverse effects to non-target aquatic species.

Based on the mysid shrimp and sheepshead minnows Maximum Acceptable Toxicant Concentration (MATC) of 0.44 to 3.4 and 0.88 to 2.2 ug/l respectively, chronic effects may be expected at the concentrations estimated above 2.0 to 12.0 ug/l. However, the chronic tests with mysid shrimp and sheepshead minnows demonstrated that effects occurred during the later stages of exposure; thus chronic effects may be unlikely if EPN occurs intermittently. Although EPN is mildly bioconcentrated, it is also rapidly depurated (eliminated from the animal's body). Significant accumulation is unlikely unless EPN is present continuously. Acute toxicity of EPN is possibly the greatest hazard. The Agency is requiring an aquatic residue monitoring study or a mesocosm study in order to better estimate environmental contamination and to complete the assessment of the persistence of EPN relative to its chronic toxicity or bioaccumulation potential.

In addition to the above aquatic study, the Agency has identified the following areas as data gaps for EPN:

- ° A fish early life-stage study. This study is required to support registration of an end-use product that is expected to be transported to water from the intended use site, when certain conditions apply:

  - Any EC_{50} or LC_{50} value in acute tests is less than 1 mg/l. (The bluegill LC_{50} with an 80% EPN formulation was 0.08 mg/l).
  - The estimated environmental concentration (EEC) in water is equal to or greater than 0.01 of any EC_{50} or LC_{50} from acute testing. (The EEC from runoff is 2.0 to 12.0 ug/l, which is approximately 2 to 15 times higher than 0.01 of the bluegill LC_{50} of 80 ug/l).
  - The EEC is less than 0.01 of the EC_{50} or LC_{50} values but the pesticide is persistent in water. (The persistence of EPN in water has not been adequately defined).

The Agency expects that aquatic environments will be exposed from use on cotton therefore a fish early life-stage study is required.

- ° An aquatic invertebrate life-cycle study. This study is required to support the registration of any end-use product that is expected to be transported to water from the intended use site, when certain conditions apply:
  - Any EC_{50} or LC_{50} value in acute tests is less than 1 mg/l. (The daphnid LC_{50} with a 99% EPN formulation was 0.32 mg/l).
  - The estimated environmental concentration (EEC) in water is equal to or greater than 0.01 of any EC_{50} or LC_{50} from acute testing. (The EEC from runoff is 2.0 to 12.0 ug/l, which is approximately 625 to 3750 times higher than 0.01 of the daphnid LC_{50} of 0.32 ug/l).
  - The EEC is less than 0.01 of the EC_{50} or LC_{50} values but the pesticide is persistent in water. (The persistence of EPN in water has not been adequately defined).

The Agency expects that aquatic environments will be exposed from use on cotton. Therefore, an aquatic invertebrate life-cycle study is required.

Existing data are also adequate to show that technical EPN is very highly toxic to waterfowl, upland game birds and passerine birds. The 8-day dietary studies conducted with technical EPN show dietary LC_{50} values for waterfowl (mallard ducks) and upland game birds (bobwhite quail) to be 168 ppm and 349 ppm, respectively (Hill et al., 1975). Avian acute oral studies have demonstrated LD_{50} values of 7.09 mg/kg (Hudson et al., 1979) and 27 mg/kg (Fink, 1976) for waterfowl (mallard ducks). Avian oral LD_{50} values for upland game birds were shown to be 53.4 mg/kg for ring-necked pheasants and 5.25 mg/kg for coturnix (Tucker and Haegele, 1971). The 24-hour percutaneous LD_{50} for mallard ducks was determined to be 400 mg/kg (Hudson et al., 1979).

Acute oral exposure is perhaps the principal route of pesticide uptake for outdoor application of granular formulations, principally through the accidental ingestion of granules adhering to food or left on the soil surface either from incomplete incorporation or spillage. Dietary exposure is the principal route for emulsifiable concentrate and wettable powder formulations. With a 24-hour percutaneous LD_{50} value of 400 mg/kg, EPN does not appear to present a dermal hazard.

The risk posed by consuming EPN granules to seven species of birds known to utilize cultivated fields is shown in Table 9. For small birds that forage for food and grit on the soil surface and that may pick up exposed granules, the number of granules required to cause death may be an important indicator of potential hazards. Although many factors may contribute to actual hazards, the Agency believes that the number of EPN granules required to cause death is large and demonstrates a wide margin of safety. In a 1984 study, Balcomb et al. (Bull. Environ. Contam. Toxicol. 33:302-307; 1984) reported that an EPN 4% granular formulation caused no mortality at doses up to 20 granules in house sparrows and 40 granules in red-winged blackbirds, confirming the Agency's predictions.

Kenaga, in a 1973 study (Environmental Quality and Safety; Vol. II; 1973; pp 166-181) reported that direct application of EPN emulsifiable concentrate and wettable powder formulations to croplands at 0.25 to 1.0 lb. ai/A would be expected to produce upper limit (maximum) initial residues over that application range of 1.75 to 7 ppm on fruits, 14.5 to 58 ppm on forage, 31 to 125 ppm on leaves and leafy crops, 27 to 110 ppm on long grasses and 60 to 240 ppm on short rangegrass. More typical limit (average) estimates are 0.37 to 1.5 ppm on fruits, 8.25 to 33 ppm on forage, 8.75 to 35 ppm on leaves and leafy crops, 23 to 92 ppm on long grasses and 31 to 125 ppm on short rangegrass. These typical residues exceed restricted use criteria (40 CFR 162.11 (c)(1)(iii)(B) and 40 CFR 162.11 (c)(2)(iii)(B)) (1/5 LC_{50} for upland game birds of 349 ppm = 69.8 ppm) on certain avian food items at the higher rates of 1.0 lb. ai/A. EPN is already a restricted use pesticide.

In a 1984 study (Toxicol. Appl. Pharmacol. 73:284-294; 1984), Hoffman and Sileo examined the effects of topical applications of EPN on mallard eggs for potential embryonic, teratogenic and neurotoxic effects. Mallard eggs were topically treated at 72 hours of incubation with 56% EPN at concentrations

Table 9. Hazard to Seven Species of Non-Target Birds from 2% and 4% Granular EPN Formulations

			Number of Granules equal to LD_{50}[1]	
Species	Body weight (g)	mg/animals (g)	2G Granules	4G Granules
Mallard (14-day)	200	0.20	3375	1687
Mallard (adult)	1200	1.20	20250	10125
Robin[2]	80	0.08	160	80
Mourning Dove[2]	100	0.10	200	100
House Sparrow[2]	20	0.02	40	20
Redwing Blackbird	50	0.05	100	50
Grasshopper Sparrow[2]	13.9	0.01	20	10
Attwater's Prairie Chicken[3] (adult)	1000	1.00	16875	8437
(14-day)	50	0.05	843	422

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[1] Weight of one granule = 0.08 mg (Balcomb et al., 1984).

- mg a.i. 2% granule = 0.08 mg X 2% = 0.0016 mg EPN/granule.
- mg a.i. 4% granule = 0.08 mg X 4% = 0.0032 mg EPN/granule.
- Mallard LD_{50} X Weight (kg) = 27.0 mg/kg X 0.200 kg = 5.4 mg/animal.

The number of 4% granules required to equal Mallard LD_{50} $= \dfrac{5.4 \text{ kg}}{0.0032 \text{ mg a.i./granule}}$

= 1687 granules equivalent to mallard LD_{50}

[2] Assuming equal sensitivity as the redwing blackbird; 3.2 mg/kg, as reported by Schafer in 1972.

[3] Assuming equal sensitivity as the mallard; 27 mg/kg as reported by Fink in 1976.

of 0.25 lb/gallon (gal), 0.75 lb/gal and 1.25 lb/gal. The study reported that external treatment of mallard eggs with EPN at the field level of application (0.25 lb/gal) was both embryotoxic (22 to 44% mortality over the dose range) and teratogenic (37 to 42% of the surviving embryos at 18 days were abnormal with cervical and axial scoliosis as well as severe edema). Brain development was also impaired as reflected by significantly ($p < 0.05$) lower brain weight in hatchlings when compared to controls. Body weight did not differ significantly. Neurotoxic effects were observed throughout embryonic development and in hatchlings as manifested by lower brain acetylcholinesterase (AChE) and brain neurotoxic esterase activity. Although this is a scientifically sound study, mallard eggs were treated with EPN under laboratory conditions and may not reflect actual field conditions. As noted in Table A, the Agency will request actual and simulated field studies in avian species after receipt and review of environmental fate studies and an avian reproduction study.

Laboratory data indicate that EPN is very highly acutely toxic to avian species. Estimated exposure on one of the vegetative groups listed above (short rangegrasses, potential food sources that have large surface area to mass ratios) is of particular concern. Additionally, topical treatment to mallard eggs resulted in embryotoxicity, neurotoxicity and teratogenicity, under laboratory conditions. Many factors can contribute to different results under field conditions. Therefore, the Agency is requiring an avian reproduction study especially in light of the fact that there are repeat applications of EPN to cotton.

2. Endangered Species.

Based on the Agency's analysis, it appears that certain use patterns of EPN may result in sufficient exposure to pose a potential hazard to certain endangered/threatened species of mammals, birds, aquatic organisms, crustaceans, reptiles and insects. (See Regulatory Position #7 in Section IV below.)

3. Environmental Fate.

The available data are insufficient for the Agency to fully assess the environmental fate and transport of EPN and the potential exposure of humans and nontarget organisms to EPN. However, available preliminary information that does not meet the Agency's data requirements does indicate general trends of EPN behavior in the environment. EPN degrades in aerobic sandy loam soil with a half-life of 4 to 8 weeks. Phenylphosphonic acid, O-ethyl phenylphosphonic acid, and O-ethyl phenylphosphonothioic acid are expected to be the main degradates under aerobic conditions. In the field, EPN dissipates with a half-life of 2 to 8 weeks from silt loam soils in Delaware and

Mississippi. EPN was detected in tailwater pit sediments and water in Kansas in 1974. EPN accumulates in pinfish tissue 700 fold and sheepshead minnow tissues 10,000 fold. Rapid depuration was noted in pinfish.

To assess the environmental fate of EPN in conjunction with its terrestrial food crop and terrestrial nonfood use patterns, the Agency is requiring the following studies:

Hydrolysis
Photodegradation on soil
Photodegradation in water
Aerobic soil metabolism
Anaerobic soil metabolism
Leaching and adsorption/desorption
Soil dissipation
Long-term soil dissipation
Rotational crops (confined and field)
Fish accumulation.

In addition, a special Droplet Size Spectrum and Spray Drift Field Evaluation Testing is being required due to the toxicity of EPN, its methods of application, and the likely exposure of off-site people and wildlife to the pesticide. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of EPN. The spray drift field evaluation is to be performed to reflect the application equipment, use patterns, and typical locations of use, which include different weather factors, in the application of EPN.

D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of EPN in a variety of raw agricultural commodities (40 CFR 180.119). Most of the tolerances were established with little or no data in conjunction with the pesticide "Spray Residue Hearings" of the late 1960s. EPA has evaluated the available residue chemistry and toxicology data and has determined that a full tolerance reassessment for EPN can not be made at this time because of extensive data gaps. However, the Agency has conducted an assessment of the tolerances relative to dietary exposure and the estimated risk of the delayed neurotoxic effect. Discussion of this is provided in subsection B, above. Since most of the required toxicology studies are missing and additional data are required in order to more precisely estimate dietary exposure and its toxicological significance, no new tolerances, either group or otherwise, will be established. The residue and toxicology data with regard to EPN tolerances are discussed in the following subsections.

1. Residue Data.

Nature of Residues in Plants.

The metabolism of EPN in plants is not adequately understood. Detailed characterization of residues in whole, 10-week old cotton plants has revealed the presence of EPN and two metabolites, O-ethyl phenylphosphonic acid and phenylphosphonic acid. The latter compound was found only in bound form. This study also revealed that ^{14}C-residues of $[^{14}C]$EPN are absorbed into plant tissues following foliar applications. No studies have been submitted that elucidate the nature of EPN residues in cottonseed (the raw agricultural commodity processed for human consumption) or in any other crops on which registered use of EPN exists. The following data are required:

- Plant metabolism studies reflecting the distribution and metabolism of benzene ring-labeled $[^{14}C]$EPN in:
    1) mature cottonseed harvested 3 days after several foliar applications at 1 lb ai/A made 4 to 5 days apart;
    2) field corn fodder and mature field corn grain harvested 14 days after several applications at 0.5 lb ai/A made 5 days apart; and
    3) mature pecans harvested 21 days following the last of several foliar applications at 7-day intervals at 3.5 lb ai/A.

  The rates stated here are based on maximum registered rates; exaggerated rates may be necessary to obtain sufficient residues in the harvested plant portion for characterization. Analyses should include hydrolysis and reextraction of plant residues and aqueous extracts to determine conjugated ^{14}C-residues of EPN. If metabolism results differ significantly among the three crops, then additional metabolism data must be submitted for a representative crop in each crop group for which registered uses of EPN exists.

Tolerances for EPN residues in or on plant comodities are currently expressed in terms of parent only. If the data required above indicate additional residues of toxicological concern, the tolerance definition will be changed accordingly. (The registrant should conduct the required metabolism studies and should submit them to the Agency for review prior to conducting the field studies described below under "Magnitude of Residues in Plants.")

Nature of Residues in Animals.

No tolerances presently exist for residues of EPN in animal products. However, the submitted data pertaining to the metabolism of EPN in animals indicate that EPN residues will transfer to tissues of poultry, but otherwise are inadequate to show the nature of those residues in poultry or other animals. The nature of EPN residues in animals is therefore not adequately understood. The following data are required:

° Metabolism studies utilizing ruminants. In these studies the animals must be dosed for three days with ring-labeled [^{14}C]EPN at a concentration in the total diet which will result in sufficient residue in the tissues and milk for characterization. Animals must be sacrificed within 24 hours of the final dose (milk must be collected twice daily). ^{14}C-Residues must be characterized and quantified in milk, muscle, fat, kidney, and liver. If residues of toxicological concern are found to transfer to the tissues and/or milk of ruminants, appropriate tolerances must be proposed.

° Metabolism studies utilizing poultry. In these studies the animals must be dosed for three days with ring-labeled [^{14}C]EPN at a concentration in the total diet which will result in sufficient residue in the tissues and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (eggs must be collected twice daily). ^{14}C-Residues must be characterized and quantified in eggs, muscle, fat, kidney, and liver. If residues of toxicological concern are found to transfer to the tissues and/or eggs of poultry, appropriate tolerances must be proposed.

Furthermore, if the nature of the residue in poultry differs significantly from that in ruminants, additional data depicting the nature of the residue in swine will be required (i.e. in the absence of rat metabolism data). If poultry and ruminant metabolism differ from that in the rat then additional swine data are required.

Residue analytical methods.

Adequate methods are available for collection of data pertaining to residues of EPN in plant commodities. These methods are based on nitrophenyl detection through colorimetry, and detection by gas chromatography. These methods have not been assigned company designations. However, the colorimetric procedure is usually referred to as "The Parathion Method" (E.I. du Pont de Nemours & Co., Inc., 1949) Another colorimetric method, commonly referred to as the "Total Phosphorus Method" (E.I. du Pont de Nemours & Co., Inc., 1949) cannot be assessed due to the absence of any recovery data. However, since no residue data generated using this method may be used to support established tolerances, due to inadequacies unrelated to the analytical method, the Agency does not require validation data for this method. The Agency recommends that the GC method (E.I. du Pont de Nemours & Co., Inc., 1977) be used in the future for data collection.

The colorimetric methods are nonspecific and therefore not suitable for enforcement work. Also, the GC method (E.I. du Pont de Nemours & Co., Inc., 1977) may not be used for enforcement purposes because no confirmatory procedure has been included in the method discussion. However, two multiple-residue enforcement methods for EPN determination are listed in the PAM Volume II, Pesticide Regulation Section 180.119. Both involve organic solvent extraction and GC detection.

It should be noted that the nature of residues in plants is not adequately understood. If the metabolism data requested above reveal additional residues of toxicological concern, additional methods for tolerance enforcement and data collection will be required.

Storage Stability.

No data have been submitted regarding the stability of EPN residues in or on plant samples in frozen storage. The following data are required:

- Storage conditions and harvest-to-analysis intervals studies.

  These studies must be submitted for the samples of corn grain, sweet corn, tomatoes, cottonseed, and soybeans from which residue data were collected and used to support established tolerances for residues in or on corn, tomatoes, beans (dried), and cottonseed. Data reflecting the storage stability of EPN in plant samples at the intervals specified must be submitted. If storage stability is poor, conclusions regarding the adequacy of tolerances for residues in or on these commodities may change.

- Data on the conditions and intervals of sample storage including fortification and recovery data.

- All residue data required in this standard must be accompanied by information pertaining to the conditions and intervals of sample storage as well as fortification and recovery data reflecting the stability of EPN at such intervals.

It should be noted that the nature of the residue in plants is not understood. If the requested plant metabolism data reveal additional metabolites of toxicological concern, data reflecting the stability of these metabolites in frozen storage will be required. Also, if residues of concern transfer to livestock, data depicting the stability of EPN and metabolites of concern in animal products will be required.

Magnitude of the Residue in Plants

Root and Tuber Vegetables Group

A crop group tolerance is not appropriate at this time for the following reasons:

- Data are required to support the established tolerances for EPN residues in or on sugar beets, a representative crop.

- Residue data are required for three additional representative crops: carrots, radishes, and potatoes. (If the registrant/petitioner proposes a use and submits residue data in support of the tolerances for residues in or on beets and turnips, no data are required for carrots and radishes.)

Beets, Rutabagas, and Turnips

There are currently no registered uses of EPN on beets, rutabagas, and turnips. However, a tolerance of 3 ppm has been established for residues of EPN in or on beets (with or without tops), rutabagas (with or without tops), and turnips (with or without tops). Since EPN has no registered use on beets, rutabagas, and turnips, the Agency will revoke the currently established tolerance for residues of EPN in or on these crops unless the registrant proposes a use and submits appropriate residue date in support of the established tolerances.

There are no Canadian or Mexican tolerance, nor are there Codex Maximum Residue Levels (MRL) for residues of EPN in or on beets, rutabagas, and turnips.

Sugar beets

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations of EPN are registered for an unspecified number of foliar applications at 1 lb ai/A using aerial equipment. A 21-day Post Harvest Interval (PHI) is in effect. Use of ultra-low volume (ULV) application equipment is permitted. Although EPN is registered for use on sugar beets, no residue data have been submitted in support of the established tolerance for residues of EPN in or on sugar beets (without tops), and no appropriate translatable data for other crops exists. Therefore, the following data are required to support the established tolerance:

- Residue data from sugar beet roots taken 21 days following the last of several foliar applications with a registered emulsifiable concentrate formulation of EPN at 1 lb ai/A, using ground and aerial equipment, including ULV equipment in separate tests. The residue tests should take place in California, Idaho, Minnesota, and North Dakota, which collectively account for approximately 67% of the United States sugar beet production.

- Data reflecting residues of EPN in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable weathered residues. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

There is no Canadian or Mexican tolerance, nor is there a Codex MRL for residues of EPN in or on sugar beets

Leaves of Root and Tuber Vegetables Group

A crop group tolerance is not appropriate at this time for the following reasons:

- EPN presently has no registered use on turnips, a representative crop. Should a use be proposed, appropriate residue data must be submitted.

- Residue data and a tolerance proposal are required for one other representative crop: sugar beet tops.

Beet Tops (greens), Rutabaga Tops, and Turnip Tops (greens).

There are currently no registered uses of EPN on beets, rutabagas, and turnips. However, a tolerance of 3 ppm has been established for residues of EPN in or on beet greens, rutabagas tops, and turnips greens. Since EPN has no registered use on beets, rutabagas, and turnips, the Agency will revoke the currently established tolerance for residues of EPN in or on beets greens, rutabaga tops (tops are not presently considered to be a raw agricultural commodity of rutabagas), and turnip greens unless the registrant proposes a use and submits appropriate residue date in support of the established tolerances.

There are no Canadian or Mexican tolerances, nor are there Codex Maximum Residue Levels (MRL) for residues of EPN in or on beet greens, rutabagas tops, and turnips greens.

Sugar Beet Tops

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations of EPN are registered for an unspecified number of foliar applications at 1 lb ai/A using ground or aerial equipment. A 21-day Post Harvest Interval (PHI) is in effect. Use of ultra-low volume (ULV) application equipment is permitted. Although EPN is registered for use on sugar beets, no tolerance has been established for residues of EPN in or on sugar beet tops at the present time.

Since sugar beet tops are a raw agricultural commodity of of sugar beets, residue data and a tolerance proposal or feeding and grazing restrictions must be proposed. Therefore, the following is required:

- Residue data from sugar beet tops harvested at regular intervals following the last of several applications with a registered EPN emulsifiable concentrate formulation at 1 lb ai/A, using ground and aerial equipment, including ULV equipment in separate tests. The residue tests should take place in California, Idaho, Minnesota, and North Dakota. A tolerance and a pregrazing interval must be proposed; alternatively, feeding and grazing restrictions may be proposed.

There is no Canadian or Mexican tolerance, nor is there a Codex MRL for residues of EPN in or on sugar beets.

Leafy Vegetables (except Brassica Vegetables) Group

A crop group tolerance is not appropriate at this time for the following reasons:

- Data are required to support the established tolerances for residues of EPN in or on spinach and lettuce. There is presently no registered use of EPN on spinach.

- Data are required on one other representative crop: celery.

Lettuce

The 4 lb/gal emulsifiable concentrate formulations of EPN is registered in California (intrastate registration) for an unspecified number of broadcast applications at 1 lb ai/A using ground or aerial equipment. A 21-day PHI is in effect. A tolerance of 3 ppm has been established for residues of EPN in or on lettuce.

No residue data have been submitted in support of the established tolerance for residues of EPN in or on lettuce, nor are appropriate translatable data available. The following data are required to support the established tolerance:

- Residue data from mature leaf and head lettuce, harvested 21 days after the last of several foliar treatments of the 4 lb/gal EPN emulsifiable concentrate formulation at 1 lb ai/A; aerial and ground applications should be represented in separate tests. The tests must take place in California, the only state in which EPN is registered for use on lettuce.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on lettuce. A Mexican tolerance of 3 ppm has been established for the residues of EPN in or on lettuce.

Spinach

There are currently no registered uses of EPN on spinach. However, a tolerance of 3 ppm has been established for residues of EPN in or on spinach. Since EPN has no registered use on spinach, the Agency will revoke the currently established tolerance for residues of EPN in or on this crop unless the registrant proposes a use and submits appropriate residue data in support of the established tolerance.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on spinach. A Mexican tolerance of 3 ppm has been established for the residues of EPN in or on spinach.

Legume Vegetables Group

A crop group tolerance is not appropriate at this time for the following reasons:

- Data are required for *Pisum* varieties (both succulent and dried).

- Additional data are required to support the established tolerances for residues of EPN in or on beans, including dried beans.

- Additional data are required to support the established tolerance for residues of EPN in or on soybeans.

- The established tolerance of 3 ppm for residues of EPN in or on beans is more than five times greater than the established tolerance of 0.05 ppm for residues of EPN in or on soybeans. If the data requirements outlined above for peas and beans are met, it may be possible to propose a crop group tolerance for legume vegetables, excluding soybeans.

Beans

The 4 lb/gal emulsifiable concentrate formulation of EPN is registered for an unspecified number of foliar applications at 0.5 lb ai/A. Two to four foliar applications at 5- to 7-day intervals, may be made at 0.125 to 0.5 lb ai/A with the EPN 25% wettable powder formulation or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations. There is also an intrastate product for use in Alabama, Arkansas, Georgia, Louisiana, Mississippi, Tennessee, and Texas which permits use of a 3 lb/gal multiple active ingredient (EPN and methyl parathion) emulsifiable concentrate on beans (dry, green, and lima) at 1.5 lb ai/A. The emulsifiable concentrate formulations may be applied by aerial equipment. The emulsifiable concentrate formulations may also be applied using ULV equipment. A 21-day PHI is in effect. A tolerance of 3 ppm has been established for residues of EPN in or on beans.

No residue data have been submitted in support of the established tolerance for EPN residues in or on beans. The Agency recommends that separate tolerances be established for residues of EPN in or on lima beans, snap beans, and dry beans. The available soybean data provide adequate support for the 3 ppm "bean" tolerance for residues of EPN in or on dry beans. However, if a crop group tolerance is desired, additional data must be submitted for dry beans since data translated from soybeans, a representative commodity of the Legume Vegetables Group, cannot be used to satisfy the data requirements for dried beans, which is also a representative commodity. Data are required to support the 3 ppm tolerance for EPN residues in or on snap beans and lima beans. The data requested below for snap beans will be translated to lima beans. The following data are required:

- Residue data from mature snap beans harvested 21 days following several foliar applications of the 3 lb/gal emulsifiable concentrate formulation, at 1.5 lb ai/A.

Separate tests must be run for both aerial and ground applications, including separate tests for the use of ULV equipment. The tests should take place in Georgia, Tennessee, and Louisiana, representative states in which use of the high rate (1.5 lb ai/A) is permitted. Data may be translated from snap beans to lima beans to support a tolerance for residues of EPN in or on lima beans.

- Residue data from snap bean cannery residue, processed from snap beans bearing measurable, weathered residues. Exaggerated rates may be necessary to achieve such residue levels. If residues are higher in cannery waste than in snap beans *per se* an appropriate feed additive tolerance must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on beans. A Mexican tolerance of 3 ppm has been established for residues of EPN in or on beans.

Soybeans

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations of EPN are registered for all necessary foliar applications at 1 lb ai/A. Ground and aerial applications may be made. The use of ULV equipment is also permitted. A 21-day PHI is in effect. A tolerance of 0.05 ppm (negligible residues) has been established for residues of EPN in or on soybeans.

The submitted data do not provide adequate support for the established tolerance for residues of EPN in or on soybeans for the following reasons: 1) geographic representation is poor; and 2) no aerial application data were submitted. The following additional data are required:

- Residue data from soybeans, harvested 21 days after the last of several applications of an emulsifiable concentrate formulation of EPN at 1 lb ai/A. The data should reflect both aerial and ground applications, including separate tests for the use of ULV equipment. The tests should be conducted in Illinois, Nebraska, Ohio, and Tennessee, which represent the major soybean production and climatic regions of the United States.

- Residue data from two soybean processed commodities (hulls and soapstock). These products must be processed from mature soybeans bearing measurable, weathered residues of EPN. Exaggerated rates may be necessary to achieve such initial residue levels. If residues are found to concentrate in hulls and soapstock, an appropriate feed additive tolerance must be proposed.

The available data are adequate to show that EPN residues will not concentrate in soybean meal. However, these data do show that EPN residues will concentrate up to 5.5 times in soybean oil. Therefore, the petitioner must propose a tolerance for residues in soybean oil that is approximately 6 times the final accepted tolerance for EPN residues in or on soybeans.

There is no Canadian nor is there a Codex MRL for residues of EPN in or on soybeans. A Mexican tolerance of 0.05 ppm (negligible residues) has been established for the residues of EPN in or on soybeans.

Foliage of the Legume Vegetables Group

A crop group tolerance is not appropriate at this time for the following reason:

- Data are required for the representative commodities, bean vines and hay (any *Phaseolus* sp.), field pea vines and straw (*Pisum* sp.) and soybean forage and straw. EPN is presently registered for use on soybeans and beans but no tolerances for residues in or on forage, vines, hay, or straw have been established.

Bean Vines and Hay

The 4 lb/gal emulsifiable concentrate formulation of EPN is registered for an unspecified number of foliar applications at 0.5 lb ai/A. Two to four foliar applications at 5- to 7-day intervals, may be made at 0.125 to 0.5 lb ai/A with the EPN 25% wettable powder formulation or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations. There is also an intrastate product for use in Alabama, Arkansas, Georgia, Louisiana, Mississippi, Tennessee, and Texas which permits use of a 3 lb/gal multiple active ingredient (EPN and methyl parathion) emulsifiable concentrate on beans (dry, green, and Lima) at 1.5 lb ai/A. The emulsifiable concentrate formulations may be applied by both aerial and ground equipment. The emulsifiable concentrate formulations may also be applied using ULV equipment. A 21-day PHI is in effect. No tolerance has been established or proposed for residues of EPN in or on bean vines or hay.

No residue data have been submitted for residues of EPN in or on bean vines or hay. The registrant must either propose a feeding and grazing restriction for these commodities, or submit tolerance proposals for residues of EPN in or on bean hay and bean vines, a pregrazing interval for vines, and the following supporting residue data:

- Residue data from bean vines and bean hay harvested after the last of several applications of the 3 lb/gal EPN emulsifiable concentrate formulation, at 1.5 lb ai/A. Tests must include both aerial and ground applications, including separate tests for the use of ULV equipment. Vines must be sampled at intervals following the last treatment and hay must be harvested 21 days after the last treatment. The tests should take place in Georgia, Tennessee, and Louisiana, representative states in which use of the high rate is permitted. Tolerances for residues in or on bean vines and hay must be proposed and a pregrazing interval for bean vines must be proposed. Alternatively, feeding and grazing restrictions may be proposed for bean vines and hay.

There are no Canadian or Mexican tolerances nor is there a Codex MRL for residues of EPN in or on bean vines or hay.

Soybeans

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations of EPN are registered for all necessary foliar applications at 1 lb ai/A. Ground and aerial applications may be made. The use of ULV equipment is also permitted. A 21-day prefeeding and pregrazing interval is in effect. A tolerance has neither been established nor proposed for residues of EPN in or on soybean forage or soybean straw.

No data have been submitted for residues in or on soybean forage or straw. The registrant must submit tolerance proposals for residues of EPN in or on soybean forage and soybean straw, and the following data:

- Residue data from soybean forage and straw, harvested 21 days after the last of several applications of an EPN emulsifiable concentrate formulation at 1 lb ai/A. The data must reflect both aerial and ground applications, and must include separate tests for use of ULV equipment. The tests should be conducted in Illinois, Nebraska, Ohio, and Tennessee. Tolerances for residues of EPN in or on soybean forage and straw must be proposed.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on soybean forage or soybean straw.

Fruiting Vegetables (Except Cucurbits) Group

A crop group tolerance is not appropriate at this time for the following reason:

- ° Residue data are required for an additional representative crop: peppers.

Tomatoes

The 25% wettable powder formulation is registered for all necessary foliar applications at 7- to 10-day intervals at 0.125 to 0.25 lb ai/A using ground equipment. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for all necessary foliar applications at 7- to 10-day intervals at 0.25 to 1 lb ai/A using aerial or ground equipment. A 21 day PHI is in effect for these registrations. In addition, there is also an intrastate product registered for use in Alabama, Arkansas, Georgis, Louisianna, Mississippi, Tennessee, and Texas that permits the use of a 3 lb/gal emulsifiable concentrate multiple-active ingredient (EPN and methyl parathion) at 1 lb ai/A as needed. A 15-day PHI is in effect for this formulation. The emulsifiable concentrate formulations may be applied with ULV equipment. A tolerance of 3 ppm has been established for residues of EPN in or on tomatoes.

The submitted data are adequate to support the established tolerance for the residues of EPN in or on tomatoes. However, the following data are required to determine whether food and/or feed additive tolerances are needed for the processed products of tomatoes:

- ° Residue data from processed tomato products, including wet pomace, dried pomace, puree, catsup and juice, processed from tomatoes bearing measurable, weathered residues of EPN. Exaggerated application rates may be necessary to achieve such initial residue levels. Should concentration of residues in processed products occur, appropriate food and/or feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on tomaotes. A Mexican tolerance of 3 ppm has been established for the residues of EPN in or on tomatoes.

Citrus Fruits Group

Citrus Fruit

The 25% wettable powder formulation is registered for foliar applications at 0.75 to 3 lb ai/A or 0.25 to 0.5 lb ai/100 gallons using ground equipment. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 0.5 to 2.25 lb ai/A using ground or aerial equipment. ULV applications of the emulsifiable concentrate formulations are also permitted. A 30-day PHI is in effect. Treated rinds may not be used for food or feed. However, the restriction prohibiting the use of the rind for food or feed in not practical since the disposition of the citrus rind is not under the control of the grower. A tolerance of 3 ppm has been established for residues of EPN in or on citrus fruit.

The submitted data are not adequate to support the established tolerance for EPN residues in or on citrus for the following reasons: 1) the residue data submitted were for pulp or peel instead of whole fruit; 2) no data reflected aerial applications; 3) no tests reflected use of an emulsifiable concentrate formulation; 4) geographic representation was poor; and 5) the representative commodities of the Citrus Fruits Group (lemons, grapefruit, oranges) were not represented. The following data are required:

- Residue data from whole sweet oranges, lemons, and grapefruit harvested 30 days after the last of several foliar applications with an emuslifiable concentrate formulation of EPN at 2.25 lb ai/A. The data must reflect both aerial and ground applications, and must include separate tests for use of ULV equipment. Tests must also reflect ground applications of the 25% wettable powder formulation at 0.5 lb ai/100 gal (>2000 gal/A). The studies involving oranges and grapefruit should take place in California and Florida; those involving lemons should take place in California and Arizona. These states represent the major United
  ates production areas of the representative citrus
  ops. If the maximum residue values determined for
  two of the three crops differ by more than a factor
  five, separate tolerances should be proposed for
  h of three crops, since a crop group tolerance would
  be appropriate. The registrant must propose a
  imum lb ai/A rate to complement the 0.5 lb ai/100 gal
  e for ground applications of the 25% wettable powder
  mulation since it is unlikely that >2000 gal/A will
  applied. The Agency recommends a maximum rate of
  lb ai/A.

- Residue data from the processed products of oranges, including dried pulp, oil, molasses, and juice, processed from oranges bearing measurable, weathered EPN residues. Exaggerated rates may be required to achieve such residue levels. If EPN is found to concentrate in any of these products, appropriate food and/or feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on citrus fruit. A Mexican tolerance of 3 ppm has been established for residues of EPN in or on citrus fruit.

Pome Fruits Group

A crop group tolerance is not appropriate at this time for the following reason:

- Data are required to support the established tolerances for residues of EPN in or on two representative crops, apples and pears.

Apples

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations and the 25% wettable powder formulation of EPN are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal beginning at petal fall and continuing at 10- to 14-day intervals as needed. The 5 lb/gal emulsifiable concentrate formulation is registered for the same type of application at 1 to 1.5 lb ai/A. A 21-day PHI is in effect. Emulsifiable concentrate formulations may be applied using aerial or ground equipment. ULV equipment is also permitted for emulsifiable concentrate formulations. Applications of EPN may not be made to McIntosh or related varieties. A tolerance of 3 ppm has been established for residues of EPN in or on apples.

The submitted data are not adequate to support the established tolerance for residues of EPN in or on apples for the following reasons: 1) maximum application rates were not represented; 2) rates in gal/A were not provided; and 3) no aerial application data were submitted. The following data are required:

- Residue data from mature apples harvested 21 days after the last of several foliar ground applications, beginning at petal fall and continuing at 10-day intervals thereafter, of the 25% wettable powder formulation. In separate tests, residue data from mature apples harvested 21 days after the last of several foliar ground applications of an emulsifiable concentrate formulation at 0.375 lb ai/100 gallons (800 gal/A). These tests must also reflect both aerial and ground ULV application of an emulsifiable concentrate formulation at 3 lb ai/A (800 gal/A rate at 0.375 lb ai/100 gal adjusted to maintain lb ai/A rate). The tests should take place in Washington, New York, Michigan, Virginia, and California, which collectively account for approximately 70 % of the United States apple production. The registrant must also propose a maximum lb ai/A rate for applications for the 25% wettable powder and emulsifiable concentrate formulations to complement the registered 0.375 lb ai/100 gal rate since it is unlikely that >800 gal/A will be applied. The Agency recommends a maximum rate of 3 lb ai/A.

° Residue data from dried pomace and juice, processed from apples bearing measurable, weathered EPN residues. Exaggerated rates may be necessary to achieve such levels. If concentration of residues occurs upon processing, appropriate food and/or feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on apples. A Mexican tolerance of 3 ppm has been established for residues of EPN in or on apples.

Pears

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations and the 25% wettable powder formulation of EPN are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal beginning at petal fall and continuing at 10- to 14-day intervals as needed. The 5 lb/gal emulsifiable concentrate formulation is registered for the same type of application at 1 to 1.5 lb ai/A. A 14-day PHI is in effect. Emulsifiable concentrate formulations may be applied using aerial or ground equipment. ULV equipment is also permitted for emulsifiable concentrate formulations. A tolerance of 3 ppm has been established for residues of EPN in or on pears.

The submitted data are not adequate to support the established tolerance for residues of EPN in or on pears for the following reasons: 1) maximum appliation rates were not represented; 2) rates in gal/A were not provided; and 3) no aerial application data were submitted for the emulsifiable concentrate formulations. The following additional data are required:

° Residue data from mature pears harvested 14 days after the last of several foliar ground applications, beginning at petal fall and continuing at 10-day intervals thereafter, of the 25% wettable powder formulation. In separate tests, residue data from mature pears harvested 14 days after the last of several foliar ground applications of an emulsifiable concentrate formulation at 0.375 lb ai/100 gallons (500 gal/A). These tests must also reflect both aerial and ground ULV application of an emulsifiable concentrate formulation at 2 lb ai/A (500 gal/A rate at 0.375 lb ai/100 gal adjusted to maintain lb ai/A rate). The tests should be conducted in California and Washington, which collectively produce approximately 73% of the domestic pears. The registrant must also propose a maximum lb ai/A rate for applications fo the 25% wettable powder and emulsifiable concentrate formulations to complement the registered 0.375 lb ai/100 gal rate since it is unlikely that >500 gal/A will be applied. The Agency recommends a maximum rate of 2 lb ai/A.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on pears. A Mexican tolerance of 3 ppm has been established for the residues of EPN in or on pears.

Quinces

There are no registered uses of EPN on quinces. A tolerance of 3 ppm has been established for residues of EPN in or on quinces. Since EPN has no registered use on quinces, the Agency will revoke the currently established tolerance for residues of EPN in or on this crop unless the registrant proposes a use and submits appropriate residue data in support of the established tolerance.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on quinces.

Stone Fruits Group

A crop group tolerance is not appropriate at this time for the following reason:

- Data are required to support the established tolerances for residues of EPN in or on fruit of the representative crops, cherries, peaches, and plums.

Apricots

The 25% wettable powder formulation is registered for foliar applications at 0.125 to 0.625 lb ai/100 gal or 0.25 lb ai/100 gal plus 1.5% light medium oil. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 1 to 1.5 lb ai/A. Foliar applications may begin at petal fall and continue at 10- to 14-day intervals as needed. A delayed dormant application may be made with the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations at

5 lb ai/A (plus 1.5% oil) at bud swell. Two or three bark applications, made in summer when borer moths appear, may be made at 0.313 to 0.75 lb gal/100 gal with the 25% wettable powder or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, or at 0.75 to 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation. A 21-day PHI is in effect. Both aerialand ground-applied foliar applications of emulsifiable concentrate formulations may be made. ULV applications are also permitted. A tolerance of 3 ppm has been established for residues of EPN in or on apricots.

No residue data were submitted in support of the established tolerance for residues of EPN in or on apricots. Data requested for peaches will be translated to assess the established tolerance for residues of EPN in or on apricots.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on apricots.

Cherries

The 25% wettable powder formulation is registered for foliar applications at 0.125 to 0.625 lb ai/100 gal or 0.25 lb ai/100 gal plus 1.5% light medium oil. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal. The 5 lb/gal emulsifiable concentrate formulation is also registered for foliar applications at 1 to 1.5 lb ai/A. Foliar applications may begin at petal fall and continue at 10- to 14-day intervals as needed. A single delayed dormant application may be made with the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations at 5 lb ai/A (plus 1.5% oil) at bud swell. Two or three bark applications, made in early to late summer when borers appear, may be made at 0.313 to 0.75 lb gal/100 gal with the 25% wettable powder or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, or at 0.75 to 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation. A 21-day PHI is in effect. Both aerial- and ground-applied foliar applications of emulsifiable concentrate formulations may be made. ULV applications are also permitted. A tolerance of 3 ppm has been established for residues of EPN in or on cherries.

The submitted data are not adequate to support the established tolerance for EPN residues in or on cherries for following reasons: 1) the data do not represent multiple foliar applications at the maximum-registered use rates; 2) aerial application data were not submitted; 3) geographic representation was not adequate; 4) no residue data from sour cherries were submitted; 5) rates were not given in lb ai/A; and 6) no tests reflected the use of 1.5% oil. The following data are required:

- Residue data from mature sweet and sour cherries, harvested 21 days following the last treatment included in the following regimen: 1) one delayed dormant application using an emulsifiable concentrate formulation at 5 lb ai/A plus 1.5% oil; 2) foliar applications, beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest, using (in separate tests):

    a) the 25% wettable powder formulation at 0.625 lb ai/100 gal (ground application);

    b) the 25% wettable powder formulation at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and

    c) ULV applications (ground and aerial, in separate tests) of an emulsifiable concentrate formulation at 3.75 lb ai/A (maximum expected gal/A rate of 1000 at 0.375 lb ai/100 gal adjusted to maintain lb ai/A rate); and

  3) two late summer bark applications of the 5 lb/gal emulsifiable concentrate formulation at 1.5 lb ai/A. In the case of ground-applied high-volume foliar applications, 1000 gallons of spray mixture should be applied per acre. The tests should be conducted in Washington and Michigan, which account for approximately 63% of the United States sweet cherry production and 84% of the United States sour cherry production. The registrant must also propose a maximum lb ai/A rate to complement the lb ai/100 gal rates for foliar applications since it is unlikely that >1000 gal/A will be applied. The Agency recommends maximum rates of 3.75 lb ai/A for the emulsifiable concentrate formulations and 6.25 lb ai/A for the 25% wettable powder formulation, unless 1.5% oil is added, in which case 2.5 lb ai/A of the 25% wettable powder would be the maximum rate.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on cherries.

Nectarines

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal beginning at petal fall and continuing to 10- to 14-day intervals as needed. The foliar applications of 5 lb/gal emulsifiable concentrate formulations may also be made at 1 to 1.5 lb ai/A. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are also registered for one delayed dormant application at 5 lb ai/A (mixed with 1.5% oil) at bud swell. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are also registered for 2 to 3 bark applications at 0.375 to 0.75 lb ai/100 gal in early to late summer when borer moths appear. The 5 lb/gal emulsifiable concentrate formulation is also registered for bark applications at 0.75 to 1.5 lb ai/A. A 21-day PHI is in effect. Both ground and aerial, foliar applications are permitted. ULV applications are also permitted. A tolerance of 3 ppm has been established for residues of EPN in or on nectarines.

No data have been submitted in support of the established tolerance for residues of EPN in or on nectarines. Data requested for peaches will be translated to assess the established tolerance for residues of EPN in or on nectarines.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on nectarines.

Peaches

The 25% wettable powder formulation is registered for foliar applications at 0.125 to 0.625 lb ai/100 gal plus 1.5% light medium oil. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal. The 5 lb/gal emulsifiable concentrate formulation is also registered for foliar applications at 1 to 1.5 lb ai/A or for ULV ground or aerial applications at 0.42 to 0.625 lb ai/A (3 to 10 gal/A). Foliar applications may begin at petal fall and continue at 10- to 14-day intervals as needed. A delayed dormant application may be made with the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations at 5 lb ai/A (plus 1.5% oil) at bud swell. Two or three bark applications, made in summer when borer moths appear, may be made at 0.313 to 0.75 lb ai/100 gal with the 25% wettable powder formulation or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, or at 0.75 to 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation. a 21-day PHI is in effect. Foliar treatments with the emulsifiable concentrate formulations may be applied by both aerial and ground equipment. ULV applications are also permitted for the emulsifiable concentrate formulations. A tolerance of 3 ppm has been established for residues of EPN in or on peaches.

The submitted data are not adequate to support the established tolerance for the residues of EPN in or on peaches for the following reasons: 1) the data do not reflect residues in samples harvested at the 21-day PHI following multiple applications at maximum permissible rates; 2) rates were not given in lb ai/A; 3) geographic representation was poor; 4) aerial application data were not submitted; and 5) no data relect use of the 25% wettable powder formulation at 0.25 lb ai/100 gal plus 1.5% oil. The following data are required to support the established tolerance:

- Residue data from mature peaches harvested 21 days following the last treatment in the following regimen:

  1) one delayed dormant application using an emulsifiable concentrate formulation at 5 lb ai/A plus 1.5% oil;

  2) foliar applications, beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest using (in separate tests):

     a) the 25% wettable powder formulation at 0.625 lb ai/100 gal (ground application);

     b) the 25% wettable powder formulation at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and

     c) ULV applications (ground and aerial, in separate tests) of an emulsifiable concentrate formulation at 2 lb ai/A (maximum expected gal/A rate of 500 adjusted to maintain lb ai/A rate);

  3) two late-summer bark applications at 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation at 1.5 lb ai/A. In the case of ground-applied high-volume foliar applications, 500 gallons of spray mixture should be applied per acre. The tests should be conducted in California and South Carolina, which produce approximately 74% of peaches in the United States. The data required for peaches will also be used for assessment of the tolerance for residues of EPN in or on nectarines and apricots. The registrant must also propose a maximum lb ai/A rate to complement the lb ai/100 gal rate for foliar applications since it is unlikely that >500 gal/A will be applied. The Agency recommends a maximum rate of 2 lb ai/A for the emulsifiable concentrate formulations and 3.1 lb ai/A for the 25% wettable powder formulation, unless 1.5% oil is added in which case 1.25 lb ai/A of the 25% wettable powder formulation would be the maximum rate.

There is no Canadian tolerance or nor is there a Codex MRL for residues of EPN in or on peaches. A Mexican tolerance for residues of EPN in or on peaches has been established at 3 ppm.

Plums (fresh prunes)

The 25% wettable powder formulation is registered for foliar applications at 0.125 to 0.625 lb ai/100 gal plus 1.5% light medium oil. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for foliar applications at 0.125 to 0.375 lb ai/100 gal. The 5 lb/gal emulsifiable concentrate formulation is also registered for foliar applications at 1 to 1.5 lb ai/A. Foliar applications may be in at petal fall and continue at 10- to 14-day intervals as needed. A delayed single delayed dormant application may be made with the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations at 5 lb ai/A (plus 1.5% oil) at bud swell. Two or three bark applications, made in summer when borer moths appear, may be made at 0.313 to 0.75 lb ai/100 gal with the 25% wettable powder formulation or the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, or at 0.75 to 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation. A 21-day PHI is in effect. Foliar treatments with the emulsifiable concentrate formulations may be applied by both aerial and ground equipment. ULV applications are also permitted for the emulsifiable concentrate formulations.

The submitted data are not adequate to support the established tolerance for residues of EPN in or on plums (fresh prunes) for the following reasons: 1) the data do not reflect multiple foliar applications at maximum-registered use rates; 2) rates were not given in lb ai/A; no data reflect aerial or ground application of an

, beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest using (in separate tests):

a) the 25% wettable powder formulation at 0.625 lb ai/100 gal (ground application);

b) the 25% wettable powder formulation at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and

c) ULV applications (ground and aerial, in separate tests) of an emulsifiable concentrate formulation at 2 lb ai/A (maximum expected gal/A rate of 500 adjusted to maintain lb ai/A rate).

3) two late-summer bark applications at 1.5 lb ai/A using the 5 lb/gal emulsifiable concentrate formulation at 1.5 lb ai/A. In the case of ground-applied high-volume foliar applications, 500 gallons of spray mixture should be applied per acre. The tests should be conducted in Oregon and Michigan, which account for approximately 69% of the United States plum production The registrant must also propose a maximum lb ai/A rate to complement the lb ai/100 gal rate for foliar applications since it is unlikely that >500 gal/A will be applied. The Agency recommends a maximum rate of 2 lb ai/A for the emulsifiable concentrate formulations and 3.1 lb ai/A for the 25% wettable powder formulation, unless 1.5% oil is added in which case 1.25 lb ai/A of the 25% wettable powder formulation would be the maximum rate.

- Residue data from dried prunes, processed from plums bearing measurable, weathered EPN residues. Exaggerated rates may be required to achieve such residue levels. If residues are found to concentrate in the dried fruit, an appropriate food additive tolerance must be proposed.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on plums (fresh prunes).

Small Fruits Group

A crop group tolerance is not appropriate at this time for the following reasons:

- Residue data and a use proposal are needed for four representative crops: blueberries, cranberries, strawberries, and blackberries (or another *Rubus* species).

- Data are required to support the established tolerance for residues of EPN in or on grapes, a representative crop.

Blackberries, Boysenberries, Dewberries, Loganberries, Raspberries, Strawberries, and Youngberries

There are currently no registered uses of EPN on blackberries, boysenberries, dewberries, loganberries, raspberries, strawberries, and youngberries. However, tolerances of 3 ppm have been established for residues of EPN in or on blackberries, boysenberries, dewberries, loganberries, raspberries, strawberries, youngberries. Since there are no registered uses of EPN for these crops the Agency will revoke the established tolerances unless the registrant proposes uses for these crops and submits appropriate residue data in support of the established tolerances.

There are no Canadian or Mexican tolerances nor are there Codex MRLs for residues of EPN in or on blackberries, boysenberries, dewberries, loganberries, raspberries, strawberries, and youngberries.

Grapes

The 25% wettable powder formulation is registered for an unspecified number of foliar applications to grapes at 0.125 to 0.25 lb ai/100 gal, and at 0.25 lb ai/A. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are also registered for foliar applications at 0.125 to 0.25 lb ai/100 gal. A 21-day PHI is in effect. Both aerial and ground applications of the emulsifiable concentrate formulation are permitted. Emulsifiable concentrate formulations may also be applied with ULV equipment. A tolerance of 3 ppm has been established for residues of EPN in or on grapes.

The submitted data are not adequate to support the established tolerance for residues of EPN in or on grapes for the following reasons: 1) no data were submitted for the emulsifiable concentrate formulations; 2) no data were submitted for aerial application of the emulsifiable concentrate formualtions; 3) samples were not collected at the 21-day PHI; and 4) geographic representation was poor. The following data are required:

- Residue data from mature grapes, harvested 21 days after the last of several foliar applications made, in separate tests, aerially (including ULV applications) and with ground equipment (including ULV and high-volume appolications) using an emulsifiable concentrate formulation at 0.25 lb ai/100 gal (250 gal/A) for high-volume applications and at 0.63 lb ai/A for ULV applications. High-volume foliar application tests (ground-applied) with the 25% wettable powder formulation must also be made at 0.25 lb ai/100 gal (250 gal/A). The ULV rate was calculated from the lb ai/100 gal rate at a maximum expected gal/A of 250 to maintain the correct rate of active ingredient per acre. The applications should be made at 10-day intervals beginning at bloom. The registrant must propose a maximum lb ai/A rate for high-volume applications since the maximum expected gal/A rate is 250. The Agency recommends that a maximum rate of 0.63 lb ai/A be proposed.

- Residue data from raisins, raisin waste, juice, wet pomace and dried pomace processed from grapes bearing measurable, weathered EPN residues. Exaggerated rates may be necessary to achieve such residue levels. If residues concentrate in any of these processed products, appropriate food and/or feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for the residues of EPN in or on grapes. A Mexican tolerance of 3 ppm has been established for the residues of EPN in or on grapes.

Tree Nuts Group

A crop group tolerance is not appropriate at this time for the following reason:

- Data must be submitted to support the established tolerances for residues of EPN in or on the representative crops: almonds, pecans, and English walnuts.

Almonds

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for an unspecified number of foliar applications at 0.125 to 0.25 lb ai/100 gal using aerial or ground equipment. Use of ULV applications equipment is also permitted for the emulsifiable concentrate formulations. The 25% wettable powder formulation is also registered for an unspecified number of foliar applications at 0.125 to 0 188 lb ai/100 gal (800 gal/A maximum), using ground equipment. A 21-day PHI is in effect. A tolerance of 0.5 ppm has been established for residues of EPN in or on almonds.

No residue data have been submitted in support of the established tolerance for residues of EPN in or on almonds. Likewise, no data or tolerance proposal have been submitted for residues of EPN in or on almond hulls. The following data are required:

- Residue data from mature almond nutmeats and corresponding hulls, harvested 21 days after the last of several foliar ground applications of an emulsifiable concentrate formulation at, 0.25 lb ai/100 gal (800 gal/A) using high-volume ground equipment and 2 lb ai/A using ULV ground equipment, in separate tests. The data should also reflect ULV aerial applications of the emulsifiable concentrate at 2 lb ai/A. The lb ai/A rate for ULV applications was calculated from the maximum expected gal/A rate (800) at 0.25 lb ai/100 gal to maintain the correct rate of active ingredient per acre. The tests should take place in California, where the majority of almonds are produced in the United States. In addition, the registrant must propose a maximum lb ai/A rate for foliar applications to complement the maximum registered lb ai/100 gal rate (0.25) since it is unlikely that >800 gal/A will be applied. The Agency recommends that a maximum rate of 2 lb ai/A be proposed.

There is no Canadian tolernce nor is there a Codex MRL for residues of EPN in or on almonds. A Mexican tolerance of 0.5 ppm has been established for residues of EPN in or on nuts.

Pecans

The 25% wettable powder formulation and the 2 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for multiple foliar treatments as needed at 0.125 to 0.5 lb ai/100 gal. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are also registered for use at 1 to 3.5 lb ai/A. Emulsifiable concentrate formulations may be applied using aerial or ground equipment. Use of ULV equipment is also permitted for applying emulsifiable concentrate formulations. A 21-day PHI is in effect. A tolerance of 0.5 ppm has been established for residues of EPN in or on pecans.

No residue data have been submitted in support of the established tolerance for residues of EPN in or on pecans. The following data are required:

° Residue data from pecans harvested 21 days after the last of several foliar applications with the 25% wettable powder formulation and, in separate tests, an emulsifiable concentrate formulation, at 0.5 lb ai/100 gal (1000 gal/A). The data should also reflect, in separate tests, both ground and aerial ULV applications of an emulsifiable concentrate formulation at 5 lb ai/A. The lb ai/A rate for ULV applications was calculated from the maximum expected gal/A rate (1000) at 0.5 lb ai/100 gal to maintain the correct rate of active ingredient per acre. The tests should take place in Georgia and New Mexico, which together produce approximately 70% of the United States pecan crop. The registrant must also propose a maximum lb ai/A rate for foliar applications to complement the maximum registered lb ai/100 gal rate (0.5) since it is unlikely that >1000 gal/A will be applied. The Agency recommends that a maximum rate of 5 lb ai/A be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on pecans. A Mexican tolerance of 0.5 ppm has been extablished for residues of EPN in or on nuts.

Walnuts

The 4 lb/gal emulsifiable concentrate formulation is registered for multiple foliar applications at 3 to 3.5 lb ai/A. The 25% wettable powder formulation and the 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are also registered for multiple foliar applications at 0.125 to 0.25 lb ai/100 gal. Emulsifiable concentrate formulations may be applied using aerial or ground equipment. Applications of emulsifiable concentrate formulations is also permitted with ULV equipment. A 21-day PHI is in effect. A tolerance of 0.5 ppm has been established for residues of EPN in or on walnuts.

No residue data have been submitted in support of the established tolerance for residues of EPN in or on walnuts. The following data are required:

- Residue data from mature walnuts, harvested 21 days after the last of several applications of the 4 lb/gal emulsifiable concentrate formulation at 3.5 lb ai/A, beginning at petal fall and continuing at 10-day intervals using, in separate tests, aerial and ground equipment, including tests using ULV equipment. Data reflecting the 25% wettable powder formulation are not required since the maximum-expected lb ai/A rate, based on 1000 gal/A, for this formulation is much lower than 3.5 lb ai/A. The tests should take place in California, where the majority of walnuts are grown. The registrant must also propose a maximum lb ai/A rate for high-volume applications to complement the maximum lb ai/100 gal rate.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on walnuts. A Mexican tolerance of 0.5 ppm has been established for residues of EPN in or on nuts.

Cereal Grains Group

A crop group tolerance is not appropriate at this time for the following reason:

- Data are required for three additional representative commodities: rice, sorghum and wheat.

Corn

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, the 25% wettable powder formulation, and the 2% and 4% granular formulations are registered for multiple foliar applications on field and sweet corn and corn grown for seed at 0.47 to 0.5 lb ai/A. The 4 lb/gal emulsifiable concentrate formulation may be similarly applied to field corn only at 0.75 lb ai/A. A 14-day PHI is in effect for all corn crops. Emulsifiable concentrate formulations may be applied both aerially and from the ground. ULV applications of emulsifiable concentrate formulations are also permitted. A tolerance of 3 ppm has been established for residues of EPN in or on corn.

The submitted data support the established tolerance for residues of EPN in or on corn; however, the Agency recommends that the registrant or petitioner propose two separate tolerances for residues of EPN in or on 1) field corn grain and 2) sweet corn (kernels plus cob with husks removed) at the currently established level of 3 ppm. Data are required, however, to determine if residues of EPN concentrate in field corn processed products. The following data are required:

- Residue data from corn processed products, including milled products, crude oil, and refined oil, processed from corn grain bearing measurable, weathered EPN residues. Exaggerated rates may be required to achieve such residue levels. If residues are found to concentrate, appropriate food and/or feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on corn. A Mexican tolerance of 3 ppm has been established for residues of EPN in or on corn.

Forage, Fodder and Straw of Cereal Grains Group

A crop group tolerance is not appropriate at this time for the following reasons:

- Additional data are required for residues in or on corn forage, fodder and silage. Tolerances must be proposed for residues in or on these commodities.
- Data are required for two additional representative crops: wheat and another cereal grain.

Corn Forage, Silage and Fodder

The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations, the 25% wettable powder formulation, and the 2% and 4% granular formulations are registered for multiple foliar applications on field and sweet corn and corn grown for seed at 0.47 to 0.5 lb ai/A. The 4 lb/gal emulsifiable concentrate formulation may be similarly applied to field corn only at 0.75 lb ai/A. A 14-day PHI is in effect for all corn crops. Emulsifiable concentrate formulations may be applied both aerially and from the ground. ULV applications of emulsifiable concentrate formulations are also permitted. There are no tolerances for residues of EPN in or on corn forage, silage or fodder.

Since EPN is registered for use on field and sweet corn, tolerances for residues in or on the following raw agricultural commodities must be proposed: forage, silage, and fodder. The submitted data are not adequate to determine appropriate tolerances for EPN residues in or on corn forage, fodder and silage. Therefore, the following data are required:

° Residue data from sweet corn forage and field corn forage, fodder and silage harvested after the last of several foliar applications of an emulsifiable concentrate formulation and in, separate tests, a granular formulation and a wettable powder formualtion at 0.75 lb ai/A. The tests should include aerial and ground ULV applications of an emulsifiable concentrate formulation. Forage must be collected at intervals following the last application. A pregrazing interval must be proposed. Fodder and silage must be harvested 14 days after the last treatment. Test should take place in Iowa, Indiana, Florida, Minnesota, California, New York, and Tennessee, which collectively represent all of the major areas of the United States where field and sweet corn foliage would be used for forage, fodder or silage.

There are no Canadian or Mexican tolerances nor is there a Codex MRL for residues of EPN in or on corn forage, silage, or fodder.

Miscellaneous Commodities

Cottonseed

The 2 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for aerial or ground multiple foliar applications at 0.313 to 1 lb ai/A. The 5 lb/gal emulsifiable concentrate formulation may also be used at a lower rate of 0.188 lb ai/A. Use of ULV equipment is permitted. A 3-day PHI is in effect. Treated forage or gin may not be fed to livestock. A tolerance of 0.5 ppm has been established for residues of EPN in or on cottonseed.

The submitted data are adequate to support the established tolerance for residues of EPN in or on the raw agricultural commodity, cottonseed. The data are also adequate to show that concentration of residues does not occur upon processing cottonseed into meal, but does occur, at up to approximately 40 times, upon processing into oil. The registrant must propose a food additive tolerance for residues of EPN in cottonseed oil. The Agency recommends that a tolerance of 20 ppm be proposed. In addition, the following data are required to determine if EPN residues concentrate in two other processed products, hulls and soapstock:

- Residue data from cottonseed hulls and soapstock, processed from cottonseed bearing measurable, weathered EPN residues. Exaggerated rates may be necessary to achieve such initial residue levels. If residues are found to concentrate in either product, appropriate feed additive tolerances must be proposed.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on cottonseed. A Mexican tolerance of 0.5 ppm has been established for residues of EPN in or on cottonseed.

Olives

The 25% wettable powder formulation is registered for an unspecified number of ground-applied foliar applications at <4 lb ai/A (0.313 to 0.625 lb ai/100 gal) or at 0.25 lb/100 gal when mixed with 1.5% light medium oil. The 4 lb/gal and 5 lb/gal emulsifiable concentrate formulations are registered for ground or aerial foliar applications at 4 to 12 lb ai/A. ULV treatments are permitted with the emulsifiable concentrate formulations. No PHI is in effect, but applications may not be made after July 15. A tolerance of 3 ppm has been established for residues of EPN in or on olives.

No data were submitted in support of the established tolerance for residues of EPN in or on olives. Therefore, the following data are required:

- Residue data from mature olives harvested from trees which received several foliar applications of the 4 lb/gal or 5 lb/gal emulsifiable concentrate formulation at 12 lb ai/A and, in separate tests, of the 25% wettable powder formulation at 0.25 lb ai/100 gal plus 1.5% light medium oil (800 gal of spray/A). The last application should be made on July 15. Residue data reflecting both aerial and ground applications, including the use of ULV equipment, with an emulsifiable concentrate formulation must be submitted. Only ground application data are required for the 25% wettable powder formulation. Tests must be conducted in California.

- Residue data from olive oil, produced from olives bearing measurable, weathered residues of EPN. Exaggerated rates may be necessary to achieve such initial residue levels. If concentration of residues does take place, an appropriate food additive tolerance must be proposed.

There is no Canadian or Mexican tolerance nor is there a Codex MRL for residues of EPN in or on olives.

Pineapples

There are currently no registered uses of EPN on pineapples. However, a tolerance of 3 ppm has been established for residues of EPN in or on pineapples. Since there is no registered use of EPN for this crop the Agency will revoke the established tolerance unless the registrant proposes a use and submits appropriate residue data in support of the established tolerance.

There is no Canadian tolerance nor is there a Codex MRL for residues of EPN in or on pineapples. A Mexican tolerance of 3 ppm has been established for residues of EPN in or on pineapples.

Magnitude of the Residue in Meat, Milk, Poultry and Eggs

Tolerances have not been proposed or established for residues of EPN in the fat, meat and meat by-products of cattle, goats, hogs, horses, sheep or poultry, or for the residues of EPN in milk or eggs.

There are no direct animal treatments for EPN on cattle, goats, hogs, horses, sheep or poultry. Tolerances have been established for residues of EPN in or on the following raw agricultural commodities on which registered uses exist and which may either be fed directly (unprocessed) or processed into commodities which may be fed to livestock: sugar beets (tops, dehydrated pulp, mollasses), beans (seeds, vines, hay, cannery residue), soybeans (seed, meal, hulls, ensiled hay, straw, forage, soapstock), citrus (pulp, molasses), apples (dehydrated pomace), almonds (hulls), corn (grain, forage, silage, fodder, cannery waste), cotton (seed, seed meal, hulls, soapstock), tomatoes (pomace) and grapes (pomace and raisin waste). Since additional data are required to support tolerances for residues of EPN in or on many of these raw agricultural commodities and data are needed to determine whether concentration of residues occurs on processing, the Agency is unable to estimate the maximum expected intake of EPN residues by cattle, poultry or swine at this time. (Refer to the section of this document entitled "Magnitude of the Residues in Plants" for details of data requirements.) Also, the nature of the residue in animals has not been adequately described. Therefore, the Agency will not assess the adequacy of the available data at the present time. However, it has been determined that ^{14}C-residues of [^{14}C] EPN transfer to the tissues of poultry and that EPN *per se* constitutes a major percentage of the residues in fat. (Refer to the section of this document entitled "Nature of the Residue in Animals" for details.) Upon receipt of the requested animal metabolism data, and data pertaining to residues in major feed items, the adequacy of the available data will be assessed and specific data requirements regarding residues in animal products will be determined.

There are no Canadian or Mexican tolerances nor are there Codex MRLs for residues of EPN in or on animal products.

2. Pesticide Monitoring Data

No information has been received to date from the United States Department of Agriculture pertaining to monitoring data, although the Agency has requested such information. Data are available, however, from the Food and Drug Administration for samples of several crops analyzed between fiscal years 1978 and 1984. These data are summarized below.

Commodity	Number of Samples	Residue Range (ppm)
Apples	1	0.06
Rice hulls	1	0.27
Rice bran	1	0.14
Wheat	1	trace
Okra	1	0.10
Peppers (1980)	1	0.38
Mustard greens	1	trace
Lettuce	1	0.02
Spices	1	0.02
Peppers (1983)	4	0.03 - 0.86
Peppers (1984)	2	0.09 - 0.59

Of the crops represented, only apples and lettuce have EPN registrations and tolerances for residues of EPN. The values reported are well below the established tolerances. The measurable EPN residues in the other corps, which do not have EPN registrations or tolerances for residues of EPN, may represent illegal use of EPN in the United States or may represent use of EPN on crops imported from other countries. Seven samples of peppers, in three different years, contained an average of 0.35 ppm EPN. However, the fifteen crop samples reported are apparently the only samples having measurable EPN residues out of 50,000 samples tested in fiscal years 1978 thru 1984. The Agency will request that FDA conduct further monitoring on these crops to determine how widespread the problem may be. Subsequently, the registrants may be asked to submit data proposing tolerances for these crops.

3. Toxicology Data and Acceptable Daily Intake (ADI)

The Acceptable Daily Intake (ADI) or Provisional Acceptable Daily Intake (PADI), if there are inadequate toxicology data to establish an ADI, and the Maximum Permissible Intake (MPI) are ways of expressing the amount of substance that the Agency believes, on the basis of the results of data from animal studies and the application of "safety" or "uncertainty" factors, may safely be ingested by humans without risk of adverse health effects. The ADI and PADI are expressed in terms of milligrams (mg) of the substance per kilogram (kg) of body weight per day (mg/kg/day).

The MPI, a related figure based on whole body exposure, is obtained by assuming a human body weight of 60 kg, and is expressed in terms of mg of substance per day (mg/day).

Section II.B. of this document discussed the regulatory history of EPN relative to the Agency's earlier assessment of neurotoxicity studies in which it concluded that the subchronic (90-day hen) delayed neurotoxicity study was inadequate and that the Agency would rely on a human cholinesterase inhibition study to assess toxicological risks to consumers and workers. However, with the subsequent submission of the new, acceptable delayed neurotoxicity studies (90-day and recovery), the Agency now believes that these two studies are more appropriate to use for risk assessments.

These assessments are provided in subsections B.9. and 10., above. In summary, the Agency concludes that the NOEL of 0.01 mg/kg/day from irreversible nerve damage in the spinal cord is appropriate to use at this time to establish a PADI. Because the NOEL is from a subchronic study, a 1000-fold safety factor (or uncertainty factor) is being used, which results in a PADI value of 0.00001 mg/kg/day. The MPI value is therefore 0.0006 mg/day. The theoretical maximum residue contribution (TMRC), which is the maximum amount of a pesticide that would be in the human diet, is 0.9859 mg/kg/day. The TMRC is based on the assumptions of an average body weight of 60 kg, a 1.5 kg daily diet, and certain food factors for the commodities with EPN tolerances (Table 4 on page 31). Based on the PADI value of 0.00001 mg/kg/day, the TMRC is 164,000 percent of the PADI. For reasons discussed in subsection B, the Agency believes this percentage is likely to be exaggerated due to unrealistic residue (tolerance) values and the assumption of 100% of crop acreage treated. Table 5 on page 32 presents a more likely assessment for five crops based on actual residue data and percent of crop treated

At this time, the Agency concludes that the present TMRC, which is a measure of the upper limit of possible dietary exposure, is far greater than what is reasonably likely to be found in practice, but there are several data gaps. When the additional chronic feeding studies necessary to establish an ADI are submitted and the extensive residue chemistry and toxicology data gaps are filled, the Agency will again evaluate the percentage of the ADI utilized. In the meantime the Agency will not approve any significant[6] new uses for EPN, including group tolerances. In the Special Review of EPN, the Agency will consider cancellation of some or all uses of EPN and will consider revoking tolerances.

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[6] "Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

4. Tolerance Reassessment Summary and Current Tolerances

It should be noted that data gaps exist for the storage stability and metabolism of EPN in plants and animals. Because the requested data and perhaps the continued adequacy of all established tolerances are dependent upon the results of the studies in the "Residue Data" section above, it is imperative that the metabolism data be collected prior to the requested residue data. Furthermore, the conclusions stated below are subject to change on receipt of the requested metabolism data and storage stability data.

Sufficient data are available to ascertain the adequacy of the established tolerances for residues of EPN in or on the following raw agricultural commodities (RACs): beans (dried), cottonseed, tomatoes, and corn. In order to be consistent with the commodity definitions listed in 40 CFR 180.34 (f), the Agency requires (1) that the tolerance for residues in or on corn be changed to two tolerances, each at 3 ppm, for residues in or on field corn grain and sweet corn (kernels plus cob with husks removed) and (2) that the tolerance for residues in or on beans be changed to three tolerances for residues in or on dried beans, at 3 ppm, and lima and snap beans for which additional data are required.

Additional data are required to support the established tolerances for residues in or on almonds, apples, apricots, beans (snap and lima only), cherries, citrus, grapes, lettuce, nectarines, olives, peaches, pears, pecans, plums, soybeans, sugar beets (without tops), and walnuts.

Also, residue data and EPN usage proposals are required to support tolerances for residues in or on beets and beet greens, blackberries, boysenberries, dewberries, loganberries, pineapples, quinces, raspberries, rutabagas, spinach, strawberries, turnips and turnip greens, and youngberries; alternatively, the Agency will move to revoke these tolerances. The Agency will also move to revoke the tolerance for residues in or on rutabaga tops since rutabaga tops are not presently considered a raw agricultural commodity (RAC) of rutabagas and no registered use of EPN on rutabagas exists.

In addition to the conclusions given above regarding established tolerances, the following requirements and recommendations are made pertaining to residues in RACs and processed products:

1) data are required to determine whether food and/or feed additive tolerances are needed for residues in the following processed products: dehydrated sugar beet pulp, sugar beet molasses, refined sugar beet sugar, soybean hulls, soybean soapstock, bean cannery residue, wet and dried tomato

pomace, tomato puree, tomato catsup, tomato juice, dried citrus pulp, citrus oil, citrus juice, citrus molasses, dried prunes, raisins, raisin waste, grape juice, wet and dried grape pomace, apple juice, wet and dried apple pomace, cottonseed hulls, cottonseed soapstock, crude and refined corn oil and corn milling products, and olive oil.

2) data and tolerance proposals for residues of EPN in or on corn forage, silage and fodder, almond hulls, and soybean forage and straw are required.

3) data and tolerance proposals for residues of EPN in or on bean vines and hay and sugar beet tops and pregrazing interval proposals for bean vines and sugar beet tops must be submitted; alternatively, feeding and grazing restrictions may be proposed.

4) food additive tolerances must be proposed for residues of EPN in cottonseed oil and soybean oil; the data indicate that a tolerance of 20 ppm will be adequate for residues in cottonseed oil; a food additive tolerance 6 times the acceptable tolerance for soybeans will be appropriate for residues in soybean oil.

5) crop group tolerances for EPN are not appropriate at this time because extensive additional residue are needed. Also, since most of the required toxicological studies are missing and data are required in order to estimate dietary exposure, no new tolerances either group or otherwise, or new uses, will be established.

The Agency's calculation of the ADI for EPN is discussed in detail in Section III. D. 3. "Toxicology Data and Acceptable Daily Intake (ADI)" above.

Tolerances issued

The present United States tolerances (40 CFR 180.119) and Mexican tolerances are listed on the following page. There are no Canadian tolerances or Codex MRL's established for EPN.

The regulatory results of the Agency's review are set out in Section IV.A., Regulatory Positions and Rationales.

EPN

Summary of Present Tolerances

Commodity	Tolerance (ppm) United States	Mexico
Apples	3.0	3.0
Apricots	3.0	---
Beans	3.0	3.0
Beets	3.0	---
Beet greens	3.0	---
Blackberries	3.0	---
Boysenberries	3.0	---
Cherries	3.0	---
Citrus fruits	3.0	3.0
Corn	3.0	3.0
Dewberries	3.0	---
Grapes	3.0	3.0
Lettuce	3.0	3.0
Loganberries	3.0	---
Nectarines	3.0	---
Olives	3.0	---
Peaches	3.0	3.0
Pears	3.0	3.0
Pineapples	3.0	3.0
Plums (fresh prunes)	3.0	---
Quinces	3.0	---
Raspberries	3.0	---
Rutabagas	3.0	---
Rutabagas tops	3.0	---
Spinach	3.0	3.0
Strawberries	3.0	3.0
Sugarbeets (but not sugar beet tops)	3.0	---
Tomatoes	3.0	3.0
Turnips	3.0	---
Turnip greens	3.0	---
Youngberries	3.0	---
Almonds	0.5	---
Cottonseed	0.5	0.5
Pecans	0.5	---
Walnuts	0.5	---
Soybeans	0.05	0.05
Nuts	---	0.5

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

Based on review and evaluation of all available data and other relevant information on EPN, the Agency has made the following determinations:

1. EPN is being placed in Special Review.

   Rationale: The Agency is initiating a Special Review for all registered uses of EPN based on the results of the delayed neurotoxicity studies, and risks to workers involved with EPN application and working in fields treated with EPN and the risks to the public from consumption of food commodities containing EPN residues. The delayed neurotoxicity effects and the risks from continued use of EPN meet or exceed the criteria for unreasonable adverse effects (40 CFR 154.7(a)(2)). The Agency is also concerned about the toxicity of EPN to aquatic and avian species and is requesting actual and simulated field studies to assess the potential toxic effects of EPN to these organisms.

   The Agency has reviewed the comments received in response to the Preliminary Notification to Registrants issued pursuant to 40 CFR 154.21. The comments do not change the Agency's position regarding the need for Special Review of EPN.

   Therefore, the Agency is placing EPN in the Special Review Process. The comments received by the Agency will be addressed in detail in the Federal Register Notice which the Agency plans to issue.

2. The Agency will continue to restrict all uses of liquid and dry (granular and wettable powder) formulations of EPN greater than 4%.

   Rationale: The restricted use classification was originally imposed on EPN liquid and dry formulations greater than 4% in January 1981 because of its acute dermal toxicity, acute inhalation toxicity and residue effects on avian species. Acute toxicity data available to the Agency show that EPN continues to meet or exceed these criteria for restricted use. Therefore, the Agency will continue to classify EPN liquid and dry formulations greater than 4% for restricted use.

3. In order to remain in compliance with FIFRA, registrants must amend their labels to incorporate a label statement concerning the histopathological changes in the spinal cord and delayed neurotoxicity to be used in conjunction with the restricted use statement.

   Rationale: The Agency believes that a statement of the reason for a product's restricted use classification should be included on the labels of restricted use products. This statement affords the product user with important information about the potential product hazard(s) that are associated with the use of the product and are the foundation for the restricted use classification.

4. The Agency does not believe that a groundwater advisory statement on EPN labeling is necessary at this time.

   Rationale: Data currently available to the Agency are insufficient to either assess the environmental fate of EPN or to characterize its leaching potential for contamination of ground water. EPN was not included in the Special Groundwater Data Call-In Notice the Agency issued on March 31, 1984. Data allowing assessment of the leaching potential and environmental fate of EPN are required.

5. Pending receipt of acute delayed neurotoxicity data on which to base the risk assessment to determine the most effective reentry interval for EPN, the Agency has determined that the following reentry intervals are necessary in order for these products to remain in compliance with FIFRA: 7 days for corn and cotton; 35 days for citrus; and 2 days for all other crops. The reentry intervals were chosen based on MOSs shown in Table 7.

   Rationale: Preliminary evaluation of recently submitted toxicity and dissipation data indicate that the 24-hour reentry interval established in 1974 for EPN under 40 CFR 170.3 (b)(2) does not provide adequate protection for fieldworkers. Therefore, the Agency is establishing these new and longer reentry intervals. However, upon receipt and review of the required acute delayed neurotoxicity data the Agency may need to revise these reentry intervals.

6. The Agency has determined that, in order to meet applicable FIFRA standards, protective clothing must be worn by mixer/loaders and applicators and that all EPN end-use product labeling must contain work safety rules, precautionary statements, and protective clothing statements. (Refer to Section IV. D. for the required protective clothing labeling).

   Rationale: EPN is an organophosphate chemical that can induce cholinesterase inhibition upon repeated significant exposure and has been shown to produce delayed neurotoxicity and histopathological changes in the spinal cord in laboratory animals. To protect workers against the acute toxicity and potential nerve damage of EPN, protective clothing (a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet; chemical resistant gloves and chemical resistant boots, shoes, or shoe coverings) is necessary to lessen worker exposure during the mixing, loading and application of EPN. The required work safety rules and precautionary labeling statements provide specific guidance for persons handling EPN products, describe the required protective clothing and equipment for use, as well as procedures for minimizing exposure to EPN contaminated materials.

7. Endangered species labeling may be required at a later date for certain use patterns of EPN.

   Rationale: EPN is toxic to certain endangered/threatened species of mammals, birds, aquatic organisms, crustaceans, reptiles and insects. The Agency, in an attempt to limit use of EPN in areas where its use may be detrimental to endangered/threatened species, will require that endangered species information be included on labeling of end-use products which contain certain terrestrial food crop and terrestrial nonfood use patterns. The required labeling will be based on Biological Opinions by the Office of Endangered Species (OES) of the Fish and Wildlife Service, U. S. Department of Interior. The Agency has developed labeling to protect endangered species from exposure to EPN and will impose these labeling requirements through a Pesticide Registration (PR) Notice which addresses not only EPN, but other pesticides with similar uses, determined to cause jeopardy to endangered species.

8. The Agency is requiring an aquatic residue monitoring study or a mesocosm study.

   Rationale: Ecological effects data currently available to the Agency are insufficient for estimating EPN's environmental contamination potential. The above studies are necessary in order for the Agency to estimate environmental contamination and to complete the assessment of the persistence of EPN relative to its chronic toxicity or bioaccumulation potential.

9. The Agency does not believe that a rotational crop restriction is necessary.

   Rationale: The Agency lacks appropriate rotational crop data at the present time to determine whether planting food or feed crops in EPN-treated soils would result in illegal residues in these crops. If required data demonstrate that follow-up crops take up EPN residues from soil, rotational crop restrictions or tolerances in those crops may be neccesary.

10. The Agency cannot conduct a full tolerance reassessment for EPN at this time.

Rationale: Data gaps exist for plant and animal metabolism, storage stability, magnitude of the residues in several raw agricultural commodities and processed food and feed items, in addition to toxicology data gaps in the area of chronic feeding/oncogenicity. Upon receipt of the data required in Table A, the Agency's conclusions with regard to the adequacy of established tolerances are subject to change. Since the data required for individual commodities are dependent on the metabolism data, the metabolism data will be obtained and reviewed prior to any required residue data.

11. No significant[7] new uses, including group tolerances, will be granted while EPN is in the Special Review process and until the Agency has received data sufficient to evaluate the dietary exposure to EPN.

Rationale: The current tolerance assessment, based on the subchronic delayed neurotoxic effect, residues at tolerance levels and 100% crop treated, shows a Theoretical Maximum Residue Contribution (TMRC) which occupies 164,000% of the Provisional Acceptable Daily Intake (PADI). While calculation of the five crops for which there are residue data, based on percent crop treated, shows roughly acceptable intake levels, many other tolerances and data gaps remain. The residue chemistry and toxicology data bases for EPN are not sufficient to assess the existing tolerances or to establish crop group tolerances. Plant and animal metabolism data and residue data on various commodities are required. The pertinent toxicology data requirments include: chronic feeding/ oncogenicity, and reproduction. (Refer to Appendix I, Table A, for a listing of residue chemistry and toxicology data required). Until these data are submitted and reviewed, the Agency cannot perform a full tolerance reassessment for EPN. The Agency believes that allowing significant dietary exposure to pesticides for which a full tolerance reassessment is impossible would not adequately protect the public.

12. The Agency has determined that the tolerances for beets and beet greens, blackberries, boysenberries, dewberries, loganberries, pineapples, quinces, raspberries, rutabagas, spinach, strawberries, turnips and turnip greens, and youngberries should be revoked because there are no registered uses of EPN for these raw agricultural commodities. Alternatively,

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[7] "Significant new use" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

the residue data and usage proposals are required for each of the above crops. This data must be submitted by September 26, 1988 to avoid revocation action by the Agency.

Rationale: There are currently no registered uses for EPN on these crops. The Agency can not evaluate the adequacy of the tolerance in the absence of directions for use.

13. The Agency will move to revoke the tolerance for residues of EPN in or on rutabaga tops.

    Rationale: Rutabaga tops are not presently considered a raw agricultural commodity of rutabagas. In addition, there is no registered use of EPN on rutabagas at the present time.

14. The Agency is requiring processing data for the following raw agricultural commodities: sugar beets, soybeans, tomatoes, citrus, prunes, grapes, apples, cottonseed, corn, and olives.

    Rationale: The Agency has no data to determine whether residues of EPN concentrate when these commodities are processed into food or feed items.

15. The Agency believes that the addition of the telephone number of the National Pesticide Telecommunications Network to the labels of all end-use EPN products is necessary in order for such products to meet applicable FIFRA standards.

    Rationale: The telephone number is included in order to provide a source of first aid information in the event of an exposure accident.

16. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing EPN as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

    Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)).

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain EPN as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

The applicant for registration or reregistration of manufacturing use products subject to this standard must comply with all terms and conditions described, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule as specified by the Agency and, when applicable, offer to pay compensation as required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRFA), as amended, 7 U.S.C. 136 (c)(2)(D). Registrants of end-use products who qualify for the Formulator's Exemption[8] must submit five (5) copies of draft labeling incorporating the unique label statements identified in Section D of the document. Registrants of end-use products who do not qualify for the Formulator's Exemption must comply with the terms and conditions set forth above for manufacturing-use registrants.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain EPN as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing EPN provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

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[8] As of the date of issue of this registration standard, there are no registrations for Technical EPN products or manufacturing-use products in the United States. Therefore, registrants of end-use products containing EPN do not qualify for the Formulator's Exemption at this time.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below.

Terrestrial Food Crop (Agricultural Crops)

- Almond
- Apple
- Apricot
- Beans
- Black-eyed Peas
- Cherry
- Citrus Citron
- Citrus Fruits
- Corn, Field
- Corn (seed crop)
- Corn, Sweet
- Cotton
- Cowpeas
- Grapefruit
- Grapes
- Green Beans
- Kumquat
- Lemon
- Lima Beans
- Lime
- Navy Beans
- Nectarine
- Olive
- Orange
- Peach
- Pear
- Pecan
- Plum
- Prune
- Red Kidney Beans
- Snap Beans
- Sour Cherries
- Soybeans
- Sugar Beets
- Sweet Cherries
- Tangelo
- Tangerine
- Tomato
- Walnut

Terrestrial Non-Food Crop

Earthworm Farms

The "EPA Index to Pesticide Chemicals" lists all registered uses of EPN, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All manufacturing-use products and end-use products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and as indicated in this Registration Standard, as appropriate to the use. Appendix II contains information on labeling requirements.

No end-use or manufacturing-use product containing EPN may be released for shipment by a registrant or producer of that product after April 30, 1988, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

No end-use or manufacturing-use product containing EPN may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after April 30, 1989, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

In addition to the above, the following information must appear on the labeling:

1. All Products

Pesticide Disposal Statement. The following pesticide disposal statement must appear on all labels:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

2. Manufacturing-use Products - All manufacturing-use products must bear the following statements:

Ingredients Statement. The ingredient statement for Manufacturing-use Products must list the active ingredient as:

O-ethyl O-p-nitrophenyl phenylphosphonothioate

Use Pattern Statements. All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

Precautionary Statements. The following statement must appear in the Environmental Hazards section of the label for all Manufacturing-use Products:

This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

3. End-use Products - Labels for end-use products must bear the statements in quotes below.

> Restricted Use Statement. All liquid formulations and any formulation greater than 4% EPN are classified as restricted use pesticides and must bear the following statement in a prominent position on the front panel of the label:
>
> "RESTRICTED-USE PESTICIDE
>
> Due to acute toxicity and demonstration of delayed neurotoxicity and irreversible nerve damage in the spinal cord in laboratory animals.
>
> For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Direct supervision for this product is defined as the Certified Applicator being physically present during mixing, loading, equiplment repair, and equipment cleaning. Applicators must ensure that all persons involved in these activities under direct supervision are informed of the precautionary statements."
>
> Precautionary Statements. The following statements must appear in the Hazards to Humans section of the label for all End-use Products:
>
> "WORK SAFETY RULES
>
> REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.
>
> Persons working with this product should have frequent blood tests of their cholinesterase levels. If the cholinesterase level falls below a critical point, no further exposure should be allowed until it has been determined by means of blood tests that the cholinesterase level has returned to normal. Before using this product consult the National Pesticide Telecommunication Network for recommendations regarding such blood tests, poisoning management, emergency treatment, and other information regarding the toxicity of EPN. The toll free number for the National Pesticide Telecommunication Network is 1-800-858-7378.
>
> CAUSES DELAYED NEUROTOXICITY IN LABORATORY ANIMALS FOLLOWING A LARGE SINGLE DOSE OR SEVERAL, SMALLER, DAILY DOSES. Neurotoxicity may occur after recovery from acute effects. No antidote for delayed neurotoxicity exists - symptomatic treatment only.

If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated area.

DO NOT APPLY THIS PRODUCT WHEN WEATHER CONDITIONS FAVOR DRIFT FROM TREATED AREAS.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away. See First Aid (Practical Treatment) section.

HANDLE THE CONCENTRATE AND LOAD THE GRANULES ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet.

Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots.

Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR part II.

If handling the concentrate with a closed system, a long sleeved shirt and long legged pants may be substituted for the protective suit and the respirator requirement is waived.

WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, DISPOSAL OF EXCESS SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS PRIOR TO THE EXPIRATION OF THE REENTRY INTERVAL:

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves and chemical resistant boots, shoes, or shoe coverings.

Application must be made only from a tractor with a completely enclosed cab or aerially with an enclosed cockpit. For these applications a long sleeved shirt and long legged pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. This clothing is inadequate to protect you during equipment repair, cleaning or reentry.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK, take off all clothes and shoes. Shower using soap and water. Wear only clean clothes. Do not use contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with EPN must be destroyed in accordance with state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS ARE PROHIBITED UNLESS IN A TOTALLY ENCLOSED VEHICLE."

Precautionary Statements. The following statements must appear in the Environmental Hazards section of the label for all end-use emulsifiable concentrate and wettable powder formulations:

"This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Runoff and drift from treated area may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops and weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

Re-entry Statements. The following statement must appear in the re-entry section of the label for all end-use products:

"Do not reenter fields treated with EPN to perform tasks requiring contact with EPN treated surfaces within: 7 days for corn or cotton crops; 35 days for citrus; or 48 hours for other crops unless the protective clothing specified in the "Precautionary Statements -- Hazards to Humans" section is worn."

Directions for Use Statements. The following statement must appear in the Directions for Use section of the label for all end-use emulsifiable concentrate and wettable powder formulations:

"Do not apply this product when weather conditions favor drift from treated areas."

Cotton. The statement listed below must appear on end-use emulsifiable concentrate and wettable powder products intended for use on cotton:

"Do not apply to blooming cotton if bees are visiting the treatment area."

Field or Sweet Corn. The statement listed below must appear on end-use emulsifiable concentrate and wettable powder products intended for use on field or sweet corn:

"Do not apply to corn during the pollenshed period if bees are visiting the treatment area."

Stone Fruits, Pome Fruits and Citrus. The statement listed below must appear on end-use emulsifiable concentrate and wettable powder products intended for use on stone fruits, pome fruits and citrus:

"Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[9]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[9] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[10], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the data requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[10] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements. This has occurred for EPN.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[11]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[11] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[12]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[12] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[11] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any product-specific data, if required by Table C.

c. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

d. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Dennis Edwards (PM 12)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition

of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Timeframe For Data Submission 2
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes	12 Months
62-2 - Certification of Ingredient Limits	TGAI	All	N/A	N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All	N/A	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	N/A	N/A	No 3/	6 Months
63-6 - Boiling Point	TGAI	All	N/A	N/A	Yes	6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation[1]	Must Additional Data be Submitted?	Time Frame for Submission 2
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes	6 Months
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes	6 Months
63-10 - Dissociation constant	PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	N/A	N/A	Yes	6 Months
63-12 - pH	TGAI	All	N/A	N/A	Yes	6 Months
63-13 - Storage Stability	TGAI	All	N/A	N/A	Yes	15 Months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	N/A	N/A	Reserved 4/	6 Months

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
6 Month Due Date is SEPTEMBER 26, 1987; 12 Month Due Date is MARCH 26, 1988.

3/ Not required because EPN is a liquid at room temperature.

4/ If samples are needed the Agency will request them.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate , [EPN]

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00109147	Yes[3] 18 Months
- Livestock	PAIRA and Plant Metabolites	Partial	00079794;00079794 00085429	Yes[4] 18 Months
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	Yes	00068437;00068905 00079807;00100090 00100099;GS0147-001 00101107	No
- Animal residues	TGAI and Metabolites	No	-	Reserved[5]
- Storage Stability Data	TGAI and Metabolites	No	-	Yes[6] 15 Months
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Root and Tuber Vegetables Group				
Beets	TEP	No	-	Yes[7]
Rutabagas	TEP	No	-	Yes[7]
Sugar beets	TEP	No	-	Yes[8] 24 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames For Data Submission[2]
§158.125 Residue Chemistry - Continued				
Turnips	TEP	No	-	Yes[7]
- Leaves of Root and Tuber Vegetables Group				
Beet tops (greens)	TEP	No	-	Yes[7]
Rutabaga tops	TEP	No	-	Yes[7]
Sugar beet tops	TEP	No	-	Yes[9] 24 Months
Turnip tops (greens)	TEP	No	-	Yes[7]
- Leafy Vegetables (Except Brassica Vegetables) Group				
Lettuce	TEP	No	-	Yes[10] 18 Months
Spinach	TEP	No	-	Yes[7]
Beans	TEP	No	-	Yes[11] 18 Months
Soybeans	TEP	Partial	00068905	Yes[12] 18 Months
- Foliage of the Legume Vegetables Group				
Beans vines and hay	TEP	No	-	Yes[13] 18 Months
Soybean forage and straw	TEP	No	-	Yes[14] 18 Months
- Fruiting Vegetables (Except Cucurbits) Group				
Tomatoes	TEP	Partial	00068437;00100090	Yes[15] 24 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [FPN]

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission[2]
§158.125 Residue Chemistry - Continued				
- Citrus Fruits Group				
Citrus Fruits	TEP	Partial	00068367;00068437	Yes[16] 24 Months
- Pome Fruits Group				
Apples	TEP	Partial	00100078;00100099	Yes[17] 24 Months
Pears	TEP	Partial	00068437;00100078 00100099	Yes[18] 18 Months
Quinces	TEP	No	-	Yes[7]
- Stone Fruits Group				
Apricots	TEP	No	-	Yes[19] 18 Months
Cherries	TEP	Partial	00068367;00068437	Yes[20] 18 Months
Nectarines	TEP	No	-	Yes[21] 18 Months
Peaches	TEP	Partial	00068367;00068437 00100078;00100099	Yes[22] 24 Months
Plums (fresh prunes)	TEP	Partial	00100078	Yes[23] 24 Months
- Small Fruits Group				
Blackberries	TEP	No	-	Yes[7]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission[2]
§158.125 Residue Chemistry - Continued				
Boysenberries	TEP	No	-	Yes[7]
Dewberries	TEP	No	-	Yes[7]
Grapes	TEP	Partial	00068367;00100078	Yes[24] 24 Months
Loganberries	TEP	No	-	Yes[7]
Raspberries	TEP	No	-	Yes[7]
Strawberries	TEP	No	-	Yes[7]
Youngberries	TEP	No	-	Yes[7]
- Tree Nuts Group				
Almonds	TEP	No	-	Yes[25] 18 Months
Pecans	TEP	No	-	Yes[26] 30 Months
Walnuts	TEP	No	-	Yes[27] 18 Months
- Cereal Grains Group				
Corn	TEP	Partial	00068437;00068905 00100088	Yes[28] 36 Months
- Forage, Fodder and Straw of Cereal Grains Group				
Corn forage, silage and fodder	TEP	Partial	00068437;00068905 00100088	Yes[29] 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frames for Data Submission[2]
§158.125 Residue Chemistry - Continued				
- Miscellaneous Crops				
Cottonseed	TEP	Partial	00068905;00089025	Yes[30] 36 Months
Olives	TEP	No	-	Yes[31] 24 Months
Pineapples	TEP	No	-	Yes[7]
- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	-	-	Yes[32]
171-4 - Special Processing Studies:	TEP			
- To Provide Residue Data for Cooked (Microwaveing and Boiling) Sweet Corn		No	-	Yes 24 Months
- To Provide Residue Data on Fresh Unwashed Tomatoes		No	-	Yes 24 Months
- A Washing Study to Provide Residue Data on Lettuce		No	-	Yes 24 Months
171-13 - Submittal of Analytical Reference Standards	PAIRA	No	-	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.125 Residue Chemistry - Continued

1. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
6 Month Due Date is SEPTEMBER 26, 1987; 15 Month Due Date is JUNE 26, 1988;
18 Month Due Date is SEPTEMBER 26, 1988; 24 Month Due Date is MARCH 26, 1989;
30 Month Due Date is SEPTEMBER 26, 1989; 36 Month Due Date is MARCH 26, 1990.

3. Data must be submitted reflecting the distribution and metabolism of benzene ring-labeled [^{14}C]EPN in (i) mature cottonseed harvested 3 days after several foliar applications at 1 lb ai/A made 4-5 days apart; (ii) field corn fodder and mature field corn grain harvested 14 days after several applications at 0.5 lb ai/A made 5 days apart; and (ii) mature pecans harvested 21 days following the last of several foliar applications at 7-day intervals at 3.5 lb ai/A. The rates stated here are based on maximum use rates; exaggerated rates may be necessary to obtain sufficient residues in the harvest portion for characterization. Analyses should include hydrolysis and reextraction of plant residues and aqueous extracts to determine conjugated ^{14}C-residues of EPN. If the metabolism results differ significantly among the three crops, then additional metabolism data must be submitted for a representative crop in each crop group for which registered uses of EPN exist. If the required data indicate additional residues of toxicological concern, the tolerance definition will be changed accordingly. The registrant should conduct the required metabolism studies and submit them to the Agency for review prior to conducting the required field studies.

4. No tolerances exist for residues of EPN in animal products. The submitted data pertaining to the metabolism of EPN in animals indicate that EPN residues will transfer to tissues of poultry, but otherwise are inadequate to show the nature of those residues in poultry or other animals. Therefore, metabolsim studies utilizing ruminants are required. Animals must be dosed for three days with ring-labeled [^{14}C]EPN at a concentration in the total diet which will result in sufficient residue in the tissues and milk for characterization. Animals must be sacrificed within 24 hours of the final dose (milk must be collected twice daily). ^{14}C-Residues must be characterized and quantified in milk, muscle, fat, kidney, and liver. If residues of toxicological concern are found to transfer to the tissues and/or milk of ruminants, appropriate tolerances must be proposed.

   Metabolism studies utilizing poultry are also required. Animals must be dosed for three days with ring-labeled [^{14}C]EPN at a concentration in the total diet which will result in sufficient residue in the tissues and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (eggs must be collected twice daily). ^{14}C-Residues must be characterized and quantified in eggs, muscle, fat, kidney, and liver. If residues

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.125 Residue Chemistry - Continued

of toxicological concern are found to transfer to the tissues and/or eggs of poultry, appropriate tolerances must be proposed. Furthermore, if the nature of the residue in poultry differs significantly from that in ruminants, additional data depicting the nature of the residue in swine will be required (i.e. in the absence of rat metabolism data). If poultry and ruminant metabolism differ from that in the rat, then additional swine data are required.

5. If residues of toxicological concern are found to transfer to the tissues and/or milk of ruminants or to the tissues and/or eggs of poultry and appropriate tolerances are proposed, then analytical methods must be submitted with the tolerance proposal.

6. No data have been submitted regarding the stability of EPN residues in or on plant samples in frozen storage. Therefore data are required. Storage conditions and harvest-to-analysis intervals must be submitted for the samples of corn grain, sweet corn, tomatoes, cottonseed, and soybeans from which residue data were collected and used to support established tolerances for residues in or on corn, tomatoes, beans (dried), and cottonseed. Data reflecting the storage stability of EPN in plant samples at the intervals specified must be submitted. If storage stability is poor, conclusions regarding the adequacy of tolerances for residues in or on these commodities may change.

   All residue data required in this standard must be accompanied by information pertaining to the conditions and intervals of sample storage as well as fortification and recovery data reflecting the stability of EPN at such intervals.

7. The registrant must submit usage proposals and data to support the established tolerance. Otherwise, the Agency will move to revoke this tolerance, as there are no registered uses for EPN on this commodity. This data must be submitted by September 26, 1988 to avoid revocation by the Agency.

8. Residue data from sugar beet roots taken 21 days following the last of several foliar applications with a registered EC formulation at 1 lb ai/A, using ground and aerial equipment, including ULV equipment (separate tests) are required. The tests should take place in CA, ID, MN, and ND which collectively account for approximately 67% of U.S. sugar beet production.

   Data reflecting residues of EPN in dehydrated pulp, molasses, and refined sugar processed from sugar beets bearing measurable weathered residues are required. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed at the time these data are submitted to the Agency.

9. Sugar beet tops are a raw agricultural commodity of sugar beets. Therefore, residue data and a tolerance proposal must be submitted or feeding and grazing restrictions must be proposed. The following data must be submitted if

§158.125 Residue Chemistry - Continued

a tolerance is proposed: residue data from sugar beet tops harvested at regular intervals following the last of several foliar applications with a registered EC formulation at 1 lb ai/A, using ground and aerial equipment, including ULV equipment (separate tests). The tests should take place in CA, ID, MN, and ND which collectively account for approximately 67% of U.S. sugar beet production.

10. The only product which contains this use at this time is an intrastate product for use in California only. When this product is called in for section 3 registration, the following data must be submitted: residue data from mature leaf and head lettuce, planted 21 days after the last of several foliar treatments of a 4 lb/gal EC formulation (only formulation with use directions for lettuce) at 1 lb ai/A. Aerial and ground applications should be represented in separate tests. The tests must take place in CA, the only registered state. If this product is to be used in other states, then appropriate geographical data must be submitted.

11. No residue data have been submitted in support of the established tolerance for EPN residues in or on beans. Separate tolerances must be established for residues of EPN in or on lima beans, snap beans and dry beans. The soybean data provide adequate support for the 3 ppm "bean" tolerance for residues in or on dry beans. Data are required to support the 3 ppm tolerances for residues in or on snap beans and lima beans. The data requested below for snap beans will be translated to lima beans. Residue data from mature snap beans harvested 21 days following several foliar applications of the 3 lb/gal EC formulation, at 1.5 lb ai/A are required. Tests must include (in separate tests) both aerial and ground applications, including the use of ULV equipment. The tests should take place in GA, TN, and LA, representative states in which use of the high rate (1.5 lb ai/A) is permitted. Data may be translated from snap beans to lima beans to support a tolerance for residues in or on lima beans. Note if a crop group tolerance for beans is desired, additional data must be submitted for dry beans; data translated from soybeans, a representative commodity of the Legume Vegetables Group, cannot be used to satisfy the data requirements for dried beans, which is also a representative commodity.

    Residue data from snap bean cannery waste, processed from snap beans bearing measurable, weathered residues are required. Exaggerated rates may be necessary to achieve such residue levels. If residues are higher in cannery waste than in snap beans *per se* an appropriate feed additive tolerance must be proposed.

12. Residue data are required from soybeans, harvested 21 days after the last of several applications of an EC formulation at 1 lb ai/A. The data should reflect both aerial and ground applications, including the use of ULV equipment (separate tests). Tests should be conducted in IL, NE, OH, and TN which represent the major soybean production and climatic regions of the U.S.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothipate [EPN]

§158.125 Residue Chemistry - Continued

Residue data from the two soybean processed commodities, hulls and soapstock are required. These products must be processed from mature soybeans bearing measurable, weathered residues of EPN. Exaggerated rates may be necessary to achieve such initial residue levels. If residues are found to concentrate in hulls and soapstock, appropriate feed additive tolerances must be proposed.

Data are adequate to show that EPN residues will not concentrate in soybean meal, but will concentrate up to 5.5x in soybean oil. A food additive tolerance for EPN residues in soybean oil that is approximately 6 times the tolerance for EPN residues in or on soybeans must be proposed at the time the required residue data for soybeans are submitted to the Agency.

13. Residue data from bean vines and bean hay harvested after the last of several applications of the 3 lb/gal EC formulation, at 1.5 lb ai/A are required. Tests must include both aerial and ground applications, including the use of ULV equipment (in separate tests). Vines must be sampled at intervals following the last treatment and hay must be harvested 21 days after the last treatment. The tests should take place in GA, TN, and IA, representative states in which use of the high rate is permitted. Tolerances for residues in or on bean vines and hay must be proposed; a pregrazing interval for bean vines must be proposed. Alternatively, feeding and grazing restrictions may be proposed for bean vines and hay.

14. Residue data are required from soybean forage and straw, harvested 21 days after the last of several applications of an EC formulation at 1 lb ai/A. The data must reflect aerial and ground applications, including the use of ULV equipment (in separate tests). Tests should be conducted in IL, NE, OH, and TN, which represent the major soybean production and climatic regions of the U.S. Tolerances for residues in or on soybean forage and straw must be proposed.

15. The submitted data are adequate to support the established tolerance for tomatoes. However, residue data from processed tomato products, including wet pomace, dried pomace, puree, catsup and juice, processed from tomatoes bearing measurable, weathered residues are required to determine whether food/feed additive tolerances are needed. Exaggerated application rates may be necessary to achieve such initial residue levels. Should concentrations of residues in processed products occur, appropriate food/feed additive tolerances must be proposed at the time these data are submitted to the Agency.

16. Residue data from whole sweet oranges, lemons, and grapefruit (representative crops of the Citrus Fruits group) harvested after the last of several foliar applications with an EC formulation (using aerial and ground application equipment, including ULV equipment, in separate tests) at 2.25 lb ai/A are required. Tests must also

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.125 Residue Chemistry - Continued

reflect ground applications of the 25% WP at 0.5 lb ai/100 gal (>2000 gal/A). The studies involving oranges and grapefruit should take place in CA and FL; those involving lemons should take place in CA and AZ; these states represent the major U.S. production areas of the representative citrus crops. If the maximum residue values determined for any two of the three crops differ by more than a factor of five, separate tolerances must be proposed for each of the three crops, since a crop group tolerance would not be appropriate. A maximum lb ai/A rate to complement the 0.5 lb ai/100 gal rate for ground applications of the 25% WP must be proposed. Since it is unlikely that >2000 gal/A will be applied, we suggest a maximum rate of 10 lb ai/A.

Residue data from the processed products of oranges, including dried pulp, oil, molasses, and juice processed from oranges bearing measurable, weathered residues are required. Exaggerated rates may be required to achieve such residue levels. If EPN is found to concentrate in any of these products, appropriate food/feed additive tolerances must be proposed at the time these data are submitted to the Agency.

17. Residue data are required from mature apples harvested 21 days after the last of several foliar ground applications (beginning at petal fall and continuing at 10-day intervals thereafter) of the 25% WP, and, in separate tests, an EC formulation at 0.375 lb ai/100 gal (800 gal/A). Tests must also reflect both aerial and ground ULV application of an EC formulation at 3 lb ai/A (800 gal/A rate at 0.375lb ai/100 gal adjusted to maintain lb ai/A rate). The tests should take place in WA, NY, MI, VA, and CA, which collectively account for approximately 70% of the U.S. apple production and the major geographic areas of production. A maximum lb ai/A rate for applications of the 25% WP and EC formulations must be proposed to complement the registered 0.375 lb ai/100 gal rate. Since it is unlikely that more than 800 gal/A will be applied, we suggest a maximum rate of 3 lb ai/A.

Residue data from dried pomace and juice, processed from apples bearing measurable, weathered residues are required. Exaggerated rates may be necessary to achieve such residue levels. If concentration of residues occurs upon processing, appropriate food/feed additive tolerances must be proposed at the time the data are submitted to the Agency.

18. Residue data are required from mature pears harvested 14 days after the last of several foliar ground applications, beginning at petal fall and continuing at 10-day intervals thereafter, of the 25% WP and in separate tests, an EC formulation at 0.375 lb ai/100 gal (500 gal/A). Tests must also reflect both aerial and ground ULV applications of an EC formulation at 2 lb ai/A (500 gal/A rate at 0.375 lb ai/100 gal adjusted to maintain lb ai/A rate). Tests should be conducted in CA and WA, which collectively produce approximately 73% of domestic pears. A maximum lb ai/A rate for application of the 25% WP and EC formulations must be proposed to complement the registered 0.375 lb ai/100 gal rate. Since it is unlikely that more than 500 gal/A will be applied, we suggest a maximum rate of 2 lb ai/A.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.125 Residue Chemistry - Continued

19. Residue data from peaches will support the tolerance for apricots.

20. Residue data are required from mature sweet and sour cherries, harvested 21 days following the last treatment included in the following regimen: (1) one delayed dormant application using an EC formulation at 5 lb ai/A plus 1.5% oil; (2) foliar applications, beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest, using (in separate tests): (a) the 25% WP at 0.625 lb ai/100 gal (ground application); (b) the 25% WP at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and, (c) ULV applications (ground and aerial, in separate tests) of an EC formulation at 3.75 lb ai/A (maximum expected gal/A rate of 1000 at 0.375 lb ai/100 gal adjusted to maintain lb ai/A rate) and two late summer bark applications of the 5 lb/gal EC at 1.5 lb ai/A. In the case of ground-applied high-volume foliar applications, 1000 gallons of spray mixture should be applied per acre. The tests should be conducted in WA and MI which account for approximately 63% of U.S. sweet cherry production and approximately 84% of U.S. sour cherry production. A maximum lb ai/A rate must be proposed to complement the lb ai/100 gal rates for (foliar) applications. Since it is unlikely that more than 1000 gal/A will be applied, we suggest maximum rates of 3.75 lb ai/A for the EC formulations and 6.25 lb ai/A for the 25% WP, unless the 1.5% oil is added, in which case 2.5 lb ai/A of the 25% WP would be the maximum rate.

21. Residue data from peaches will support the nectarine tolerance.

22. Residue data are required for mature peaches harvested 21 days following the last treatment in the following regimen: (i) one delayed dormant application using an EC formulation at 5 lb ai/A plus 1.5% oil; (ii) foliar applicat beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest using (in separate tests): (a) the 25% WP at 0.625 lb ai/100 gal (ground application); (b) the 25% WP at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and, (c) ULV applications (ground and aerial, in separate tests) of an EC formulation at 2 lb ai/A (maximum expected gal/A rate of 500 adjusted to maintain lb ai/A rate); (iii) two late-summer bark applications at 1.5 lb ai/A using the 5 lb/gal EC. In the case of ground-applied high-volume foliar applications, 500 gallons of spray mixture should be applied per acre. The tests should be conducted in CA and SC which produce approximately 74% of U.S. peaches. The data required here will also be used for assessment of the tolerance for residues of EPN in or on nectarines and apricots. A maximum lb ai/A rate must be proposed to complement the lb ai/100 gal rates for (foliar) applications. Since it is unlikely that more than 500 gal/A will be applied, we suggest a maximum rate of 2 lb ai/A for the EC formulations and 3.1 lb ai/A for the 25% WP, unless 1.5% oil is added in which case 1.25 lb ai/A of the 25% WP would be the maximum rate.

23. Residue data are required from mature plums, harvested 21 days following the last treatgment included in the following regimen: (i) one delayed dormant application using an EC formulation at 5 lb ai/A plus 1.5% oil; (ii) foliar

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applications, beginning at petal fall and continuing at 10-day intervals until 21 days prior to harvest, using (in separate tests): (a) the 25% WP at 0.625 lb ai/100 gal (ground application); (b) the 25% WP at 0.25 lb ai/100 gal plus 1.5% light medium oil (ground application); and, (c) ULV applications (ground and aerial, in separate tests) of an EC formulation at 2 lb ai/A (maximum expected gal/A rate of 500 adjusted to maintain lb ai/A rate); and, (iii) two late-summer bark applications of the 5 lb/gal EC at 1.5 lb ai/A. In the case of ground-applied high-volume foliar applications, 500 gallons of spray mixture should be applied per acre. The tests should be conducted in OR and MI which account for approximately 69% of U.S. plum production. A maximum lb ai/A rate must be proposed to complement the lb ai/100 gal rates for (foliar) applications. Since it is unlikely that more than 500 gal/A will be applied, we suggest maximum rates of 2 lb ai/A for the EC formulations and 3.1 lb ai/A for the 25% WP, unless 1.5% oil is added in which case 1.25 lb ai/A if the 25% WP
would be the maximum rate.

Residue data from dried prunes, processed from plums bearing measurable, weathered residues are required. Exaggerated rates may be required to achieve such residue levels. If residues are found to concentrate in the dried fruit, an appropriate food additive tolerance must be proposed at the time the data are submitted to the Agency.

24 Residue data from mature grapes, harvested 21 days after the last of several foliar applications made, in separate tests, aerially (including ULV applications) and with ground application equipment (including ULV and high volume applications) using an EC formulation at 0.25 lb ai/100 gal (250 gal/A) for high-volume applications and at 0.63 lb ai/A (ULV applications). High-volume foliar application tests (ground-applied) with the 25% WP must also be made at 0.25 lb ai/100 gal rate at a maximum expected gal/A of 250 to maintain the correct rate of active ingredient per acre. The applications should be made at 10-day intervals beginning at bloom. A maximum expected ai/A rate for high-volume applications must be proposed. Since the maximum expected gal/A rate is 250, we suggest that a maximum rate of 0.63 lb ai/A be proposed.

Residue data from raisins, raisin waste, juice, wet pomace and dried pomace processed from grapes bearing measurable, weathered residues are required. Exaggerated rates may be necessary to achieve such residue levels. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed at the time the data are submitted to the Agency.

25. Residue data from mature almond nutmeats and corresponding hulls, harvested 21 days after the last of several foliar ground applications of an EC formulation at, in separate tests, 0.25 lb ai/100 gal (800 gal/A) using

high-volume ground equipment and 2 lb ai/A using ULV ground equipment are required. The data should also reflect ULV aerial applications of the EC at 2 lb ai/A. (The lb ai/A rate for ULV applications was calculated from the maximum expected gal/A rate (800) at 0.25 lb ai/100 gal to maintain the correct rate of active ingredient per acre.) The tests should take place in CA where the majority of almonds are produced. A maximum lb ai/A rate for foliar applications to complement the maximum registered lb ai/100 gal rate (0.25) should be proposed. Since it is unlikely that more than 800 gal/A will be applied, we suggest that a maximum rate of 2 lb ai/A be proposed.

26. Residue data from pecans harvested 21 days after the last of several foliar applications with the 25% WP and, in separate tests, an EC formulation, at 0.5 lb ai/100 gal (1000 gal/A) are required. The data should reflect, in separate tests, both ground and aerial ULV applications of an EC formulation at 5 lb ai/A. (The lb ai/A rate for ULV applications was calculated from the maximum expected gal/A rate (1000) at 0.5 lb ai/100 gal to maintain the correct rate of active ingredient per acre.) The tests should take place in GA and NM which together produce approximately 70% of the U.S. pecan crop. A maximum lb ai/A rate for foliar applications to complement the maximum registered lb ai/100 gal rate (0.5) must be proposed. Since it is unlikely that more than 1000 gal/A will be applied, we suggest that a maximum rate of 5 lb ai/A be proposed.

27. Residue data are required from mature walnuts, harvested 21 days after the last of several applications of the 4 lb/gal EC at 3.5 lb ai/A, beginning at petal fall and continuing at 10-day intervals using, in separate tests, aerial and ground application equipment, including tests using ULV equipment. Data reflecting the 25% WP are not required since the maximum expected lb ai/A rate, based on 1000 gal/A, for this formulation is much lower than 3.5 lb ai/A. The tests should take place in CA where the majority of the walnuts are grown. A maximum lb ai/A rate for high volume applications must be proposed to complement the maximum lb ai/100 gal rate.

28. Data are adequate to support the established tolerance for residues of EPN in or on corn. However, data are required to determine if residues of EPN concentrate in field corn processed products. Therefore, residue data from corn processed products, including milled products, crude oil and refined oil processed from corn grain bearing measurable, weathered residues are required. Exaggerated rates may be required to achieve such residue levels. If residues are found to concentrate, appropriate food/feed additive tolerances must be proposed at the time these data are submitted to the Agency.

29. Residue data from sweet corn forage and field corn forage, fodder and silage harvested after the last of several foliar applications of an EC and in, separate tests, a G and a WP at 0.75 lb ai/A are required. The tests should include aerial and ground ULV applications of an EC formulation. Forage must be collected at intervals following the

§158.125 Residue Chemistry - Continued

last application; a pregrazing interval must be proposed. Fodder and silage must be harvested 14 days after the last treatment. Tests should take place in IA, IN, FL, MN, CA, NY, and TN which collectively represent all of the major areas of the U.S. where field and sweet corn foliage would be used for forage, fodder or silage.

30. The submitted data are adequate to support the established tolerance for residues of EPN in or on cottonseed. The data are also adequate to show that concentration of residues does not occur upon processing cottonseed into meal, but does occur, up to approximately 40x, upon processing into oil. Therefore, a food additive tolerance for residues of EPN in cottonseed oil must be proposed at the time the data on cottonseed hulls and soapstock are submitted. We suggest that a tolerance of 20 ppm be proposed. In addition, the following data are required to determine if EPN residues concentrate in two other processed products, hulls and soapstock. Residue data from cottonseed hulls and soapstock, processed from cottonseed bearing measurable, weathered residues are required. Exaggerated rates may be necessary to achieve such initial residue levels. If residues are found to concentrate in either product, appropriate feed additive tolerances must be proposed at the time these data are submitted to the Agency.

31. Residue data from mature olives harvested from trees which received several foliar applications of the 4 or 5 lb/gal EC at 12 lb ai/A and, in separate tests, of the 25% WP at 0.25 lb ai/100 gal puls 1.5% light medium oil (800 gal of spray/A). The last application should be made on July 15. Residue data reflecting both aerial and ground applications, including the use of ULV equipment, with an EC formulation must be submitted. Only ground application data are required for the 25% WP. Tests must be conducted in CA.

Residue data from olive oil produced from olives bearing measurable, weathered residues of EPN are required. Exaggerated rates may be necessary to achieve such initial residue levels. If concentration of residues does take place, an appropriate food additive tolerance must be proposed at the time these data are submitted to the Agency.

32. There are no direct animal treatments for EPN. However, tolerances are established on raw agricultural commodities with registered uses which may either be fed directly (unprocessed) or processed into commodities which may be fed to livestock. Since additional data are required to support tolerances for residues of EPN in or on many of these raw agricultural commodities and data are needed to determine whether concentration of residues occurs on processing, we are unable to estimate the maximum expected intake of EPN residues by cattle, poultry, or swine at this time. Upon receipt of the requested animal metabolism data, and data pertaining to residues in major feed items, the adequacy of the available data will be assessed and specific data requirements regarding residues in animal products will be determined.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,	No	-	Yes 9 Months
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,	No	-	Yes 9 Months
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes 9 Months
161-4 - In Air	TGAI or PAIRA	A	No	-	No
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,	No	-	Yes 27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes 27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	No	-	No
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	No	-	No
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,	No	-	Yes 12 Months
163-2 - Volatility (Lab)	TEP	A	No	-	No
163-3 - Volatility (Field)	TEP	A	No	-	No

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]	
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	-	No	-	No	
164-3 - Forestry	TEP	-	No	-	No	
164-4 - Combination and Tank Mixes			No	-	No	
164-5 - Soil, Long-term	TEP	A	No	-	Yes[4]	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes[5]	50 Months
165-3 - Irrigated Crops	TEP		No	-	No	
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP	A	No	-	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.130 Environmental Fate - Continued

1. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
9 Month Due Date is DECEMBER 26, 1987; 12 Month Due Date is MARCH 26, 1988;
15 Month Due Date is JUNE 26, 1988; 27 Month Due Date is JUNE 26, 1989;
39 Month Due Date is JUNE 26, 1990; 50 Month Due Date is MAY 26, 1991.

4. Based on the aerobic soil metabolism study or field dissipation studies, if 50% dissipation is reached by the time of subsequent applications no long-term study is required.

5. This study is required only if significant residues of concern are found in the confined study.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A	Yes	00100099	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A	Yes	00145678	No
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A	Yes	00057028	No
81-4 - Eye Irritation - Rat	TGAI	A	Yes	00100099	No
81-5 - Dermal Irritation - Rat	TGAI	A	Yes	00100099	No
81-6 - Dermal Sensitization	TGAI	A	No	-	Yes 9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A	Yes	00159372	No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding :	TGAI				
- Rodent, and		A	Yes	00158874	No
- Non-rodent (Dog)		A	Yes	00158890	No
82-2 - 21-Day Dermal - Rabbit	TGAI	A	Yes	00152760	No
82-3 - 90-Day Dermal - Rat	TGAI	A	No	-	No[4]
82-4 - 90-Day Inhalation: - Rat	TGAI	A	Yes	00161799	No
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A	Yes	00003945	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.135 Toxicology - Continued					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species:	TGAI				
- Rodent, and		A	No		Yes[5]
- Non-rodent (Dog)		A	No		Yes[5]
83-2 - Oncogenicity - 2 species:	TGAI				
- Rat (preferred), and		A	No		Yes[6]
- Mouse (preferred)		A	No		Yes[6]
83-3 - Teratogenicity - 2 species:	TGAI				
- Rat		A	No	00162934	No
- Rabbit		A	No	00163019	No
83-4 - Reproduction - Rat 2-generation	TGAI	A	No		Yes[7]
MUTAGENICITY TESTING					
84-2 - Gene Mutation (Ames Test)	TGAI	A	Yes	00153511 00160618	No
84-2 - Structural Chromosomal Aberration	TGAI	A	Yes	00153510 00153509	No
84-2 - Unscheduled DNA Synthesis	TGAI	A	Yes	001535089	No

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.135 Toxicology - Continued					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Partial	00158920	Yes[8] 24 Months
85-3 - Dermal Absorption	PAIRA	A	No		Yes[9] 12 Months
85-X - Acute Delayed Neurotoxicity - Mechanism Recovery - Hen	TGAI	A	Yes	00160200	No[10]
85-Y - Neurotoxicity in Hens Single Dose NOEL	TGAI	A	No	-	Yes[11] 12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate , [EPN]

§158.135 Toxicology - Continued

1. Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data, except where indicated otherwise.
9 Month Due Date is DECEMBER 26, 1987 ; 12 Month Due Date is MARCH 26, 1988 ;
24 Month Due Date is MARCH 26, 1989 .

4. Based on expected exposure patterns this study is not required.

5. The chronic feeding studies are due by May 1, 1989.

6. The oncogenicity studies are due by October 1988.

7. The 2-generation reproduction study is due November 1, 1987.

8. Male rats must be treated with the same dose used for females. Metabolites must be identified. Potential excretion in bile must be investigated.

9. Contact EPA for protocol.

10. The only requirement for this previously submitted study was a reevaluation of the spinal cord slides in groups 7, 8, 9 and 10 in order to determine if the hens showing signs of neurotoxicity can be distinguished by the pattern of abnormalities in the cord. This reevaluation has been completed. There are no further requirements for this study.

11. A single dose study in hens to determine a NOEL for delayed neurotoxicity by observation and histopathology. 20 hens per dose to allow sacrifice of 10 hens per dose at 21 and 40 days post dose.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/	
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	Yes	00162999 00163515	No	27 Months
132-1 - Soil Dissipation	TEP	A	No	-	No	
133-3 - Dermal Exposure	TEP	A	No	-	No	
133-4 - Inhalation Exposure	TEP	A	No	-	No	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No	-	Yes[4]	12 Months
201-1 - Drift Field Evaluation	TEP	A	No	-	Yes[4]	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.140 Reentry Protection continued					

1. Composition: TEP = Typical end-use product.

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
12 Month Due Date is MARCH 26, 1988 ; 27 Month Due Date is JUNE 26, 1989 .

4. The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the drop spectrums that are associated with actual field use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	A	Yes	00111931;05000975	No
- Upland Game Bird, and		A	Yes	00022923 00077299	No
- Waterfowl		A	Yes	00022923	No
71-3 - Wild Mammal Toxicity	TGAI	A	No	-	No
71-4 - Avian Reproduction	TGAI				
- Upland Game Bird, and		A	No	-	Yes[4] 24 months
- Waterfowl		A	No	-	Yes[4] 24 months
71-5 - Simulated Field Testing	TEP				
- Mammals, and		A	No	-	Reserved[5]
- Birds		A	No	-	Reserved[5]
- Actual Field Testing	TEP				
- Mammals, and		A	No	-	Reserved[5]
- Birds		A	No	-	Reserved[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.145 Wildlife and Aquatic Organisms - Continued					
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity	TGAI				
- Coldwater Fish Species, and		A	Yes	00100093	No
- Warmwater Fish Species		A	Yes	00100093	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	Yes	00100093;05009242 00002875;00085219	No
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI				
- Fish		A	Yes	00066341	No
- Mollusk		A	Yes	00066341	No
- Shrimp		A	Yes	00066341	No
72-4 - Fish Early Life Stage, and - Aquatic Invertebrate Life-Cycle	TGAI	A			
a. Freshwater fish			No	-	Yes[6] 15 months
b. Shrimp			Yes	00066341	No
c. Freshwater invertebrate			No	-	Yes[6] 15 months

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.145 Wildlife and Aquatic Organisms - Continued					
72-5 - Fish - Life-Cycle	TGAI	A	Yes	00066341	No
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product				
- Crustacean		A	No	-	7
- Fish		A	No	-	7
- Insect Nymph		A	No	-	7
- Mollusk		A	No	-	7
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A	No	-	Yes[8] 24 Months
- Actual Field Testing -Aquatic Organisms		A	No	-	Yes[8] 48 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

§158.145 Wildlife and Aquatic Organisms - Continued

1. Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. Data must be submitted within the indicated time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
15 Month Due Date is JUNE 26, 1988; 24 Month Due Date is MARCH 26, 1989.
48 Month Due Date is March 26, 1991.

4. Data are required to support repeated applications to cotton.

5. This data requirement is reserved pending receipt and evaluation of certain environmental fate data requirements and review of required avian reproduction study.

6. It is expected that aquatic environments will be exposed from the use on cotton, corn and soybeans to the extent that this study is required.

7. See Table A, data requirements for Accumulation Studies under Section 158.130, 165-4 and 165-5.

8. Residue monitoring in aquatic environments adjacent to cotton and corn producing areas are required. In lieu of monitoring, a mesocosm study may be submitted. An acceptable protocol must be submitted prior to initiating these studies. Acceptable environmental fate data, when submitted, may alter these requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		3		
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		3		
122-1 - Vegetative Vigor	TGAI		3		
122-2 - Aquatic Plant Growth	TGAI		3		
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		3		
123-2 - Vegetative Vigor	TGAI		3		
123-3 - Aquatic Plant Growth	TGAI		3		
TIER III					
124-1 - Terrestrial Field	TEP		3		
124-2 - Aquatic Field	TEP		3		

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1. Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. These data are not required in accordance with §158.150.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: O-ethyl-O-p-nitrophenyl phenylphosphonothioate ' [EPN]

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [3]
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	Yes[4] 15 Months
141-4 - Honey bee subacute feeding study	(Reserved)[5]				
141-5 - Field testing for pollinators	TEP	A	No	-	No[6]

1. Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3. Data must be submitted within the following time frame. The beginning date for these time frames is March 26, 1987, the date of the Agency's most recent Data Call In Notice calling in these data.
   15 Month Due Date is JUNE 26, 1988.

4. Data from the acute contact test indicate high toxicity, therefore, data on residual toxicity are required.

5. Requirement reserved pending the development of test methodology.

6. The data reviewed do not indicate the need for a field study.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission[3]
§158.155 Nontarget Insect - Continued					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)				
142-1 - Aquatic insect life-cycle study	(Reserved)				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)				

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1. Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2. The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop: D=Aqautic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)[1]	Bibliographic Citation[1]	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [2]	
§158.120 Product Chemistry					
Product Identity:					
61-1 - Product Identity and Disclosure of Ingredients	MP	N/A	-	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	N/A	-	Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	N/A	-	Yes	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	N/A	-	Yes	12 Months
62-2 - Certification of Limits	MP	N/A	-	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	N/A	-	Yes	12 Months
Physical and Chemical Characteristics					
63-2 - Color	MP	N/A	-	Yes	6 Months
63-3 - Physical State	MP	N/A	-	Yes	6 Months
63-4 - Odor	MP	N/A	-	Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)[1]	Bibliographic Citation [1]	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [2]
§158.120 Product Chemistry (Continued)				
Physical and Chemical Characteristics (Continued)				
63-7 - Density, Bulk Density, or Specific Gravity	MP	N/A	-	Yes 6 Months
63-12 - pH	MP	N/A	-	Yes 6 Months
63-14 - Oxidizing or Reducing Action	MP	N/A	-	Yes 6 Months
63-15 - Flammability	MP	N/A	-	Yes 6 Months
63-16 - Explodability	MP	N/A	-	Yes 6 Months
63-17 - Storage Stability	MP	N/A	-	Yes 15 Months
63-18 - Viscosity	MP	N/A	-	Yes 6 Months
63-19 - Miscibility	MP	N/A	-	Yes 6 Months
63-20 - Corrosion Characteristics	MP	N/A	-	Yes 15 Months
Other Requirements:				
64-1 - Submittal of samples	MP	N/A	-	Yes 6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)[1]	Bibliographic Citation [1]	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission [2]
§158.120 Product Chemistry (Continued)				

MP = Manufacturing-use Product; R = Required; CR = Conditionally Required

1/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
6 Month Due Date is OCTOBER 30, 1987 ; 12 Month Due Date is APRIL 30, 1988 ;
15 Month Due Date is JULY 30, 1988 .

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL:
O-ethyl O-p-nitrophenyl phenylphosphonothioate [EPN]

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Time Frame for Data Submission 3/	
§158.135 Toxicology					
ACUTE TESTING					
81-1 - Acute Oral Toxicity - Rat	MP	No	-	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	No	-	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	No	-	Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	No	-	Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	Yes	9 Months

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1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
- 9 Month Due Date is JANUARY 30, 1988.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

SUMMARY-3

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

••Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

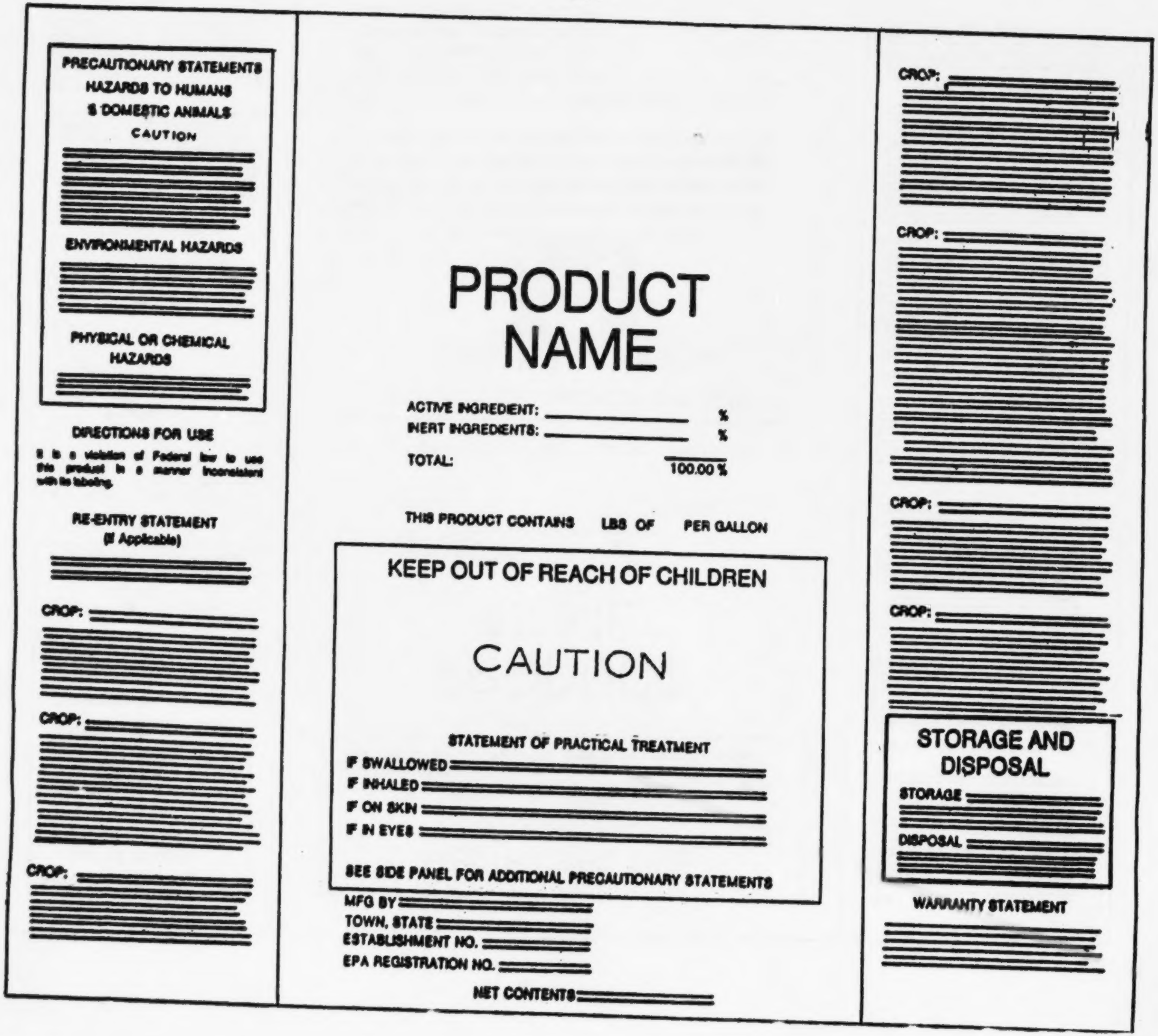
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinquishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
$ DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

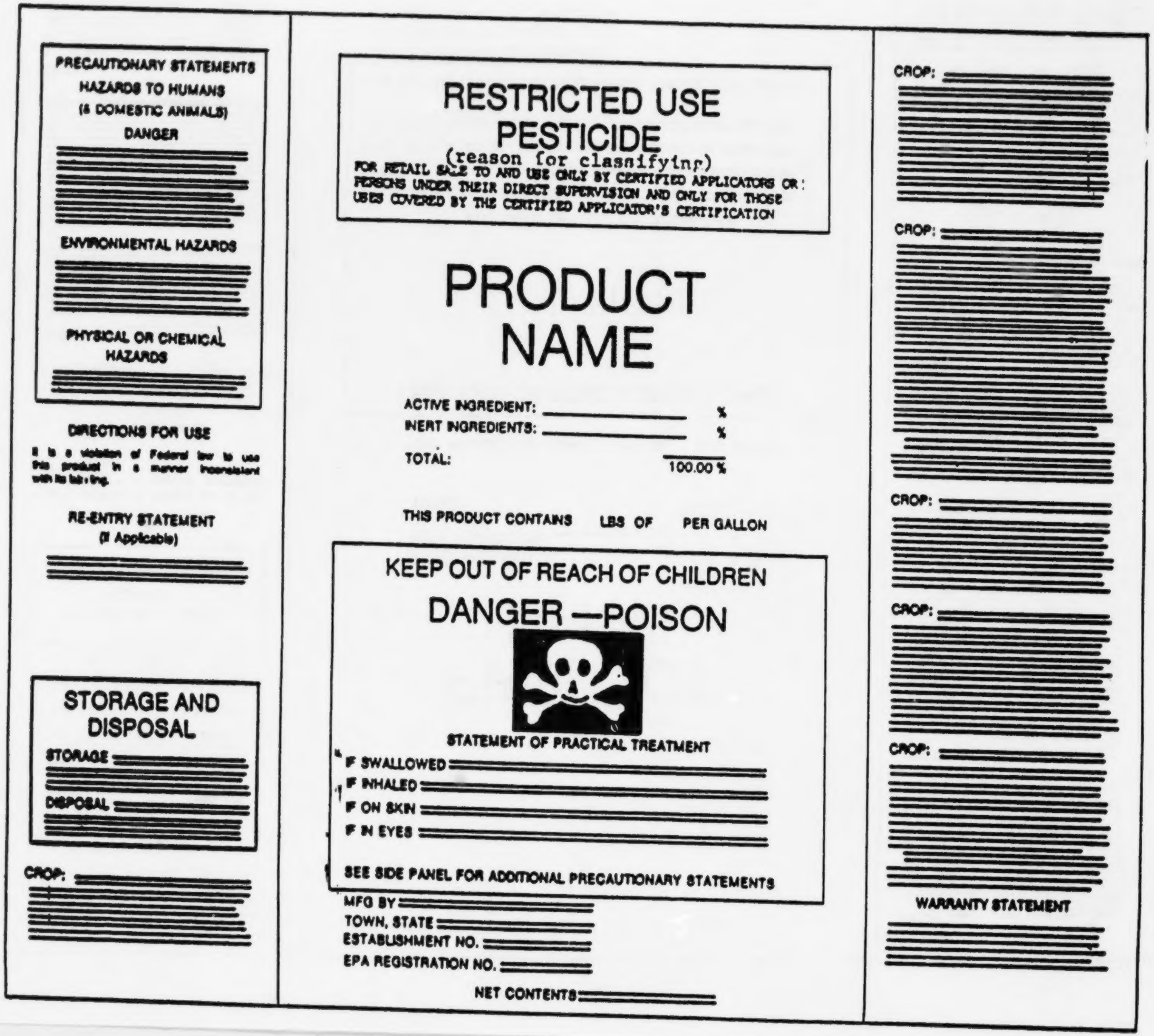
CROP:

CROP:

CROP:

STORAGE AND DISPOSAL
STORAGE
DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

~~(e) *Conditional registration.* Any application for which a review of scientific data is needed, other than an application which the Agency determines may be considered for unconditional registration under paragraph (d) of this section, will be treated as an application for conditional registration under FIFRA sec. 3(c)(7) and will be reviewed and acted upon as set forth in §§ 162.160 through 162.177.~~

~~(f) *Denial of registration.* The Administrator shall deny an application reviewed under paragraph (d) of this section if any of the requirements of paragraph (d)(2) of this section are not met, or if there are insufficient data to make the required determinations.~~

~~(1) *Notification.* Promptly after making a determination to deny a registration, the Administrator shall notify the applicant by certified letter of the denial of registration and shall set forth the reasons and factual basis for the determination and the conditions, if any, which must be satisfied in order for the registration to be approved.~~

~~(2) *Opportunity for remedy by applicant.* (i) The applicant will have 30 days from the date of receipt of the certified letter to take the specified corrective action.~~

~~(ii) The applicant may petition the Administrator to withdraw his application. The Adminstrator may, in his discretion, deny any petition for withdrawal and proceed to issue a notice of denial in accordance with paragraph (f)(3) of this section.~~

~~(3) FEDERAL REGISTER *publication.* If the applicant fails to remedy the deficiency of his registration application, the Administrator shall promptly issue in the FEDERAL REGISTER a notice of denial of registration. Such notice shall set forth the reasons and factual basis for the denial and shall contain the name and address of the applicant, the product name, the name and percentage by weight of each active ingredient in the product, the proposed patterns of use, and the proposed classification.~~

~~(4) *Hearing rights.* Within 30 days following publication of the denial in the FEDERAL REGISTER, the applicant or any interested party with the written authorization of the applicant may request a hearing pursuant to section 6(b) of the Act and Part 164 of this chapter. If no hearing is timely requested, the denial shall become effective at the end of the 30 days.~~

~~(g) *Disposition of material submitted with the application.* The test data and other information submitted with an application shall become a part of the official file of the Agency for that application or registration. Except as provided by section 10 of the Act, within 30 days after the registration of a pesticide, the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to his decision shall be made available for public inspection.~~

~~[48 FR 34004, July 26, 1983]~~

~~§ 162.8 Data to be furnished by applicant.~~

~~(a) An applicant for registration, reregistration, or amendment of a registration under FIFRA sec. 3(c)(5) shall furnish data as required by the Agency to determine whether his application may be approved under this Part.~~

~~(b) An applicant shall submit with his application any factual information regarding adverse effects of the pesticide on the environment or man that:~~

~~(1) Has been obtained by him or has come to his attention; and~~

~~(2) Insofar as he is aware, has not previously been submitted to the Agency.~~

~~Such information shall include, but shall not be limited to, published or unpublished laboratory studies and accident experience.~~

~~[48 FR 34005, July 26, 1983]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device,

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement—*(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical .attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food. Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use':

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a)-(b) [Reserved]~~

~~(c) *Use classification—(1) Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified~~

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of
>
> Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. USE INDEX APPENDIX

EPA Compendium of Acceptable Uses

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE*

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041801

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:

Tech	(93%)
FI	(80%)
G	(0.26%, 1%, 2%, 4%)
WP	(5%, 25%)
EC	(2 lb/gal, 3 lb/gal, 4 lb/gal, 5 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: All liquid formulations and any formulation greater than 4 percent are RESTRICTED USE PESTICIDES. Do not use in combination with bordeaux or zinc sulfate-lime sprays. Do not combine emulsifiable concentrate formulation with wettable powder formulation unless previous use of this mixture has proven physically compatible and safe to plants. Do not allow entry into treated fields within 24 hours after treatment, unless full protective clothing is worn.

HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT: Wear a protective suit of 1 or 2 pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Heatlh under the provisions of 30 CFR Part II. If handling the concentrate with a closed system, a long sleeved shirt and long legged pants may be substituted for the protective suit and the respirator requirement is waived.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, AND DURING EARLY REENTRY TO TREATED AREAS: Wear a protective suit of 1 or 2 pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves and chemical resistant boots, shoes, or shoe coverings. Application must be made only from a tractor with a completely enclosed cab or aerially with an enclosed cockpit. For these applications a long sleeved shirt and long legged pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. This clothing is inadequate to protect you during equipment repair, cleaning or reentry.

Refer to appropriate labeling for ENDANGERED SPECIES RESTRICTIONS.

Bee Caution:

EPN is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply EPN or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Agricultural Crop Tolerances:

Beets (with or without tops)	3 ppm
Beet greens	3 ppm
Blackberry	3 ppm
Boysenberry	3 ppm
Dewberry	3 ppm
Lettuce	3 ppm
Loganberry	3 ppm
Pineapple	3 ppm

*EPN

GENERAL WARNINGS AND LIMITATIONS (continued)

Quince	3 ppm
Raspberry	3 ppm
Rutabaga (with or without tops)	3 ppm
Rutabaga (tops)	3 ppm
Spinach	3 ppm
Strawberry	3 ppm
Turnips (with or without tops)	3 ppm
Turnips greens	3 ppm
Youngberry	3 ppm

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not use in home plantings nor apply with hand equipment. Do not use in mist blower type or thermal aerosol type (fog) equipment. Consult your State Cooperative Agricultural Extension Service for proper timing of applications and for instructions regarding posting treated areas. When a dosage range is given, use the lower rate on small young plants or when infestation is light. Use the higher rate on large or mature plants or when infestation is heavy.
For fruits, apply the first cover spray following bloom or with the first sign of infestation. Repeat as needed unless otherwise specified. Granular formulations may be applied by aircraft.
For wettable powder formulations, apply per acre rates in a minimum of 20 gallons of water per acre by high pressure hydraulic equipment.
For emulsifiable concentrate formulations, apply per acre rates in a minimum of 1 to 10 gallons of water by aircraft or in a minimum of 3 to 10 gallons of water by low volume ground equipment. Labeling claims varying minimum gallonages depending on crop growth and size. If low volume ground equipment is desired, the rate per 100 gallons should be adjusted in order to maintain the correct rate of active ingredient per acre. For aerial applications, flagging must be by fully automated mechanical means or by humans working in totally enclosed vehicles. Emulsifiable concentrate formulations may be tank mixed with methyl parathion.
Do not apply when weather conditions favor drift from areas treated.

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
)3001AA	Almond		0.5 ppm 21 day preharvest interval through 2 pounds per acre for foliar application. Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom.
IAMABA	Peach twig borer	0.25 lb/ 100 gal (4, 5 lb/gal EC)	Foliar application.
LAVAAA	Spider mites (including European red mite, Pacific spider mite and twospotted spider mite)	0.125-0.188 lb/100 gal [max 800 gal/A] (25% WP) (4, 5 lb/gal EC)	

EPA Compendium of Acceptable Uses

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
)4001AA)4003AA	Apple Pear		3 ppm 21 day preharvest interval (apples) or 14 day preharvest interval (pears) through 4.5 pounds per acre for foliar application. Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom. Do not use on McIntosh or related varieties (apples).
TBUCSA NASAVA	Codling moth Plum curculio	0.25-0.375 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 1-1.5 lb/A (5 lb/gal EC)	Foliar application. Apply at petal fall and repeat at 10 to 14 day intervals as needed.
TBUAGA	Fruittree leafroller	0.188-0.375 lb/100 gal (25% WP) (4, 5 lb/gal EC)	Foliar application.
:RAXALA	Pear psylla	0.125-0.375 lb/100 gal (25% WP) (4, 5 lb/gal EC)	
[LAVAAA	Spider mites (including European red mite, Pacific spider mite, Schoene spider mite, twospotted spider mite and Willamette spider mite)	0.125-0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC)	
/04001AA	(Apple)		
ITBUCSA	Codling moth	0.5 lb/100 gal [900 gal/A] (4 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
ITBUAGA	Fruittree leafroller		
IRAXALA	Pear psylla		
INASAVA	Plum curculio		

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple (continued)		
AVAAA	Spider mites (including European red mite, Pacific spider mite, Schoene spider mite, twospotted spider mite and Willamette spider mite)	[MAI] 4.5 lb/A (3 lb/gal EC)	
05001AA	Apricot		3 ppm 21 day preharvest interval through 3 pounds per acre for foliar and bark applications. Delayed dormant application through 5 pounds per acre. Do not make more than 1 application during the delayed dormant period. Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom.
05002AA	Cherry		
05003AA	Nectarine		
05005AA	Plum		
05006AA	Prune		
05004AA			
RAHAWG	Cottony peach scale (crawlers)	0.313 lb/ 100 gal (25% WP) (4, 5 lb/gal EC)	Foliar application.
RAHAJG	Lecanium scales (crawlers)		
TBUAGA	Fruittree leafroller	0.188 lb/ 100 gal (25% WP) (4, 5 lb/gal EC)	
RAKBPG	Olive scale (crawlers)	0.625 lb/ 100 gal (25% WP) or 0.25 lb/ 100 gal [plus 1.5% light medium oil] (25% WP)	

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apricot cluster (continued)		
LAVAAA	Spider mites (including European red mite, Pacific spider mite, two-spotted spider mite and Willamette spider mite)	0.125-0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC)	
RAHAWG	Cottony peach scale (crawlers)	5 lb/A [plus 1.5% oil] (4, 5 lb/gal EC)	Delayed dormant application. Apply once at the time flower buds begin to swell.
RAHAJG	Lecanium scales (crawlers)		
RAKBPG	Olive scale (crawlers)		
TBUCJA	Oriental fruit moth		
TBQALA	Lesser peachtree borer	0.313-0.75 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 0.75-1.5 lb/A (5 lb/gal EC)	Bark application. Make application during appearance of the moths in early to late summer. Apply 2 or 3 sprays to trunk from ground to scaffold limbs timed with moth flight.
TBQAHA	Peachtree borer		
TBUCJA	Oriental fruit moth	0.25-0.375 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 1-1.5 lb/A (5 lb/gal EC)	Foliar application. Apply at petal fall and repeat at 10 to 14 day intervals as needed.
NASAVA	Plum curculio		
/28001AA	Beans (including blackeyed peas, cowpeas, lima beans, red kidney beans, and snap beans)		3 ppm 21 day preharvest interval through 1.5 pounds per acre for foliar application. Do not feed treated vines to livestock.
ITBCDCA	Armyworm complex (including beet armyworm and yellowstriped armyworm)	0.5-1 lb/A (2, 3, 4 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
ITBMBWA	Beet webworm		

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beans (continued)		
	Pest list continued from previous page.		
QAMACA	Rapid plant bug	[MAI] 0.5-1 lb/A (2, 3 lb/gal EC)	
OABADA	Serpentine leafminer complex		
QAMATA	Tarnished plant bug		
MOAAAA	Thrips		
TBCBOA	Tomato fruitworm		
TBMCCA	European corn borer	0.25 lb/A (25% WP)	Foliar application. Make 2 to 4 applications beginning 5 to 7 days after eggs are laid.
NAPAFA	Mexican bean beetle	0.125-1 lb/A (25% WP) (2, 4, 5 lb/gal EC)	Foliar application. For Mexican bean beetle, make 2 to 4 applications starting 5 to 7 days after eggs are laid.
LAVBEA	Twospotted spider mite	[MAI] 0.125-1 lb/A (3 lb/gal EC)	May be formulated with methyl parathion.
RACAAA	Aphids	[MAI] 0.25-1.5 lb/A (2, 3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
TBCDCA	Armyworm complex (including beet armyworm, southern armyworm, and yellowstriped armyworm)		
NAMADA	Flea beetles		
RAFAAA	Leafhoppers		
QAMARA	Lygus bugs		
LAAABA	Mites (including russet mite)		
TBCCZA	Climbing cutworms	[MAI] 0.67 lb/A (2 lb/gal EC)	
INBUAAA	Darkling beetles	[MAI] 0.5-0.94 lb/A (3 lb/gal EC)	
IQAQAAA	Stink bugs	[MAI] 0.5-1 lb/A (2, 3 lb/gal EC)	

EPA Compendium of Acceptable Uses

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cherry		See Apricot cluster.
2000AA	Citrus Fruits (including grapefruit, kumquat, lemon, lime, orange, tangelo, and tangerine)		3 ppm 30 day preharvest interval through 8 pounds per acre for foliar application. Do not use treated rinds for food or feed. Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom.
AVARA	Citrus red mite	0.25-0.375 lb/100 gal (25% WP)	Use limited to FL. Foliar application.
		0.5 lb/100 gal or 2-3 lb/A (25% WP) or 0.5 lb/A (4, 5 lb/gal EC)	Foliar application.
IOCAOA	Citrus thrips	1.5-2 lb/A (25% WP) (4, 5 lb/gal EC)	Foliar application.
IOCAOA TBUAGA TBUALA TAAAFA	Citrus thrips Fruittree leaf roller Orange tortrix Orangeworms	4-8 lb/A (4 lb/gal EC)	Foliar application.
TBUAGA TBUALA	Fruittree leaf-roller Orange tortrix	0.75-2.25 lb/A (25% WP) (4, 5 lb/gal EC)	
TAAAFA	Orangeworms	1.25-1.5 lb/A (25% WP) (4, 5 lb/gal EC)	

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O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
28006AA	Corn, Field		3 ppm 14 day preharvest interval through 0.75 pound per acre for foliar application. Do not apply during the pollenshed period if bees are visiting the treatment area. May be tank mixed with methomyl.
TBCCFA	Armyworm	0.47-0.5 lb/A (4, 5 lb/gal EC) [MAI] 0.25-0.5 lb/A (2, 3 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
ITBCCZA	Climbing cutworms	[MAI] 0.188-0.5 lb/A (2, 3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
INAMBHJ	Corn rootworms (adults)	0.23-0.5 lb/A (4, 5 lb/gal EC) [MAI] 0.188-0.25 lb/A (3 lb/gal EC)	Foliar application. Apply when pests first appear (to protect silk from damage). May be formulated with methyl parathion.
IRACDKA IQAQAAA	Corn leaf aphids Stink bugs	[MAI] 0.188-0.25 lb/A (3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
ITMBCCA	European corn borer	0.2-0.5 lb/A (1%, 2%, 4% G) (25% WP) (2, 3, 4, 5 lb/gal EC) or 0.75 lb/A (4 lb/gal EC) or	Foliar application. Apply 10 days after eggs first hatch or when 75 percent of the plants show evidence of feeding in leaf whorls. Repeat 7 to 10 days later if new evidence of leaf feeding is present. For second brood, apply when eggs begin to hatch. May be formulated with methyl parathion.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Corn, Field (continued)		
		[MAI] 0.2-0.5 lb/A (2, 3 lb/gal EC)	
ITBCCOA	Fall armyworm	[MAI] 0.188-0.5 lb/A (3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
ITBMAYA	Southwestern corn borer	0.5 lb/A (4, 5 lb/gal EC) [MAI] 0.25-0.5 lb/A (3 lb/gal EC)	Foliar application. For second to third generation borer, apply when 10 percent of plant population have eggs masses. Repeat at 5 to 10 day intervals as needed. May be formulated with methyl parathion.
ILAVAAA	Spider mites (including Pacific spider mite and twospotted spider mite)	0.75 lb/A (4 lb/gal EC) [MAI] 0.5 lb/A (3 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
ITBCCXA	Surface feeding cutworms	[MAI] 0.5 lb/A (2 lb/gal EC)	Foliar application. Formulated with methyl parathion.
/28005BA	Corn (seed crop)		3 ppm 14 day preharvest interval through 0.5 pound per acre for foliar application (forage and fodder). Do not apply during the pollenshed period if bees are visiting the treatment area.
INAMBHJ	Corn rootworms (adults)	0.25-0.5 lb/A (4 lb/gal EC)	Foliar application to seed crop. Apply when pests first appear (to protect silk from damage).
ITMBCCA	European corn borer	0.2-0.5 lb/A (2, 4% G) (25% WP) (4 lb/gal EC)	Foliar application to seed crop. Apply when 25 percent of the plants show first brood whorl feeding. Repeat in 7 days if new feeding damage occurs. For second brood, apply at pollen shedding and while plants are in the green silk stage.

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
15005AA	Corn, Sweet		3 ppm 14 day preharvest interval through 0.75 pound per acre for foliar application. Do not apply during the pollenshed period if bees are visiting the treatment area. May be tank mixed with methomyl.
TBCCFA	Armyworm	0.47-0.5 lb/A (4, 5 lb/gal EC) [MAI] 0.25-0.5 lb/A (2, 3 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
TBCCZA	Climbing cutworms	[MAI] 0.188-0.5 lb/A (2, 3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
NAMBHJ	Corn rootworms (adults)	0.23-0.5 lb/A (4, 5 lb/gal EC) [MAI] 0.188-0.25 lb/A (3 lb/gal EC)	Foliar application. Apply when pests first appear (to protect silk from damage). May be formulated with methyl parathion.
IRACDKA IQAQAAA	Corn leaf aphids Stink bugs	[MAI] 0.188-0.25 lb/A (3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
ITMBCCA	European corn borer	0.2-0.5 lb/A (1%, 2%, 4% G) (25% WP) (2, 3, 4, 5 lb/gal EC) or 0.75 lb/A (4 lb/gal EC) or	Foliar application. Apply when 25 percent of the plants show evidence of leaf feeding. Repeat at 5 day intervals as long as leaf feeding is evident. One to 3 applications may be required. For control of second brood borers, apply when eggs begin to hatch. May be formulated with methyl parathion.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Corn, Sweet (continued)		
		[MAI] 0.2-0.5 lb/A (2, 3 lb/gal EC)	
BCCOA	Fall armyworm	[MAI] 0.188-0.5 lb/A (3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
BMAYA	Southwestern corn borer	0.5 lb/A (4-5 lb/gal EC) [MAI] 0.25-0.5 lb/A (3 lb/gal EC)	Foliar application. For second to third generation borer, apply when 10 percent of plant population have eggs masses. Repeat at 5 to 10 day intervals as needed. May be formulated with methyl parathion.
AVAAA	Spider mites (including Pacific spider mite and twospotted spider mite)	0.75 lb/A (4 lb/gal EC) [MAI] 0.5 lb/A (3 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
TBCCXA	Surface feeding cutworms	[MAI] 0.5 lb/A (2 lb/gal EC)	Foliar application. Formulated with methyl parathion.
28007AA	Cotton		0.5 ppm (cottonseed) 3 day preharvest or hand picking interval through 1 pound per acre for foliar application. Do not feed treated forage or gin trash to livestock. Do not apply to blooming cotton if bees are visiting the treatment area. May be tank mixed with chlordimeform, chlordimeform hydrochloride and methomyl.
RACAAA	Aphids (including cotton aphid)	[MAI] 0.125-0.67 lb/A (2, 3 lb/gal EC)	Foliar application. Formulated with methyl parathion.

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
TBCCNA	Beet armyworm	[MAI] 0.5-1 lb/A (2, 3 lb/gal EC)	
TABACA	Saltmarsh caterpillar		
TBCCSA	Cabbage looper	[MAI] 0.25-1 lb/A (2, 3 lb/gal EC)	
TAYAHA	Cotton leafperferator		
TBCCQA	Yellow striped armyworm		
TBCAOA	Cotton leafworm	[MAI] 0.167-0.94 lb/A (2, 3 lb/gal EC)	
QAMARA	Lygus bugs (and other mirids)		
NBUAAA	Darkling beetles	[MAI] 0.94 lb/A (3 lb/gal EC)	
NAPAFA	Mexican bean beetle		
OABADA	Serpentine leafminer		
TBCCLA	Southern armyworm		
TBMBWA	Sugarbeet webworm		
LAJAHA	Tomato russet mite		
LAVBEA	Twospotted spider mite		
TBCCOA	Fall armyworm	[MAI] 0.125-0.56 lb/A (2, 3 lb/gal EC)	
LAVAAA	Spider mites		
QAMBDA	Fleahoppers (including cotton fleahopper)	[MAI] 0.0635-0.94 lb/A (2, 3 lb/gal EC)	
ITBMBVA	Garden webworm	[MAI] 0.168-0.67 lb/A (2, 3 lb/gal EC)	
IVABAAA	Grasshoppers		
IMOAAAA	Thrips		

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O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
QAMACA QAMATA	Rapid plant bug Tarnished plant bug	[MAI] 0.67-0.94 lb/A (2, 3 lb/gal EC)	
TBCCNA QAMACA DABADA TBCCLA QAMATA	Beet armyworm Rapid plant bug Serpentine leaf-miner complex Southern armyworm Tarnished plant bug	1 lb/A (4 lb/gal EC)	Foliar application.
NASAHA	Boll weevil	0.5-1 lb/A (2, 4, 5 lb/gal EC)	Foliar application. Apply when plants are fruiting and 10 to 25 percent of squares are punctured. Repeat at 5 day intervals as needed.
		0.188-0.94 lb/A (5 lb/gal EC)	Foliar application. Apply the lower dosage for overwintered adults. Apply the higher dosage for middle and late season control.
		[MAI] 0.1-0.67 lb/A (2, 3 lb/gal EC)	May be formulated with methyl parathion.
ITBCBOA ITAMADA ITBCBNA	Bollworm Pink bollworm Tobacco budworm	0.94-1 lb/A (2, 4, 5 lb/gal EC)	Foliar application. For bollworm, apply when eggs and 4 to 5 larvae per 100 terminals are found or before larvae have infested bolls.
		[MAI] 0.33-1 lb/A (2, 3 lb/gal EC)	May be formulated with methyl parathion.
IRAFCFA ITBCADA ILAVAAA IMOAAAA ITBCCQA	Cotton fleahoppers Cotton leafworm Spider mites Thrips Yellowstriped armyworm	0.313-0.625 lb/A (2, 4, 5 lb/gal EC)	Foliar application. Apply when pests first appear and repeat at 4 to 5 day intervals as needed.

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O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
1014AA	Grapes		3 ppm 21 day preharvest interval through 0.75 pound per acre for foliar application.
BGBDA	Grape berry moth	0.25 lb/A (25% WP) or 0.25 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 0.75 lb/A (4 lb/gal EC)	Foliar application.
AFAOA	Grape leafhopper	[MAI] 0.75 lb/A (3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
LAVAAA	Spider mites (including European red mite, Pacific spider mite, two-spotted spider mite and Willamette spider mite)	0.125-0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC) [MAI] 0.75 lb/A (3 lb/gal EC)	Foliar application. May be formulated with methyl parathion.
	Nectarine		See Apricot cluster.
28014AA	Olive		3 ppm Foliar application through 12 pounds per acre. Do not apply after July 15.
RAHAWC RAHAJC	Cottony peach scale (crawlers) Lecanium scales (crawlers)	0.313 lb/100 gal [max 4 lb/A] (25% WP) or 4-6 lb/A (4 lb/gal EC) or 8-12 lb/A (4, 5 lb/gal EC)	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Olive (continued)		
AKBPG	Olive scale (crawlers)	0.625 lb/ 100 gal [max 4 lb/A] (25% WP) or 0.25 lb/ 100 gal [plus 1.5% light medium oil] (25% WP) or 4-6 lb/A (4 lb/gal EC) or 8-12 lb/A (4, 5 lb/gal EC)	
5004AA	Peach		3 ppm 21 day preharvest interval through 3 pounds per acre for foliar and bark applications. Delayed dormant application through 5 pounds per acre. Do not make more than 1 application during the delayed dormant period. Do not apply when trees or a substantial number of weeds in the orchard/grove are in bloom.
NASAVA QAMATA	Plum curculio Tarnished plant bug	[MAI] 0.375 lb/100 gal (5% WP)	Delayed dormant and foliar application. Apply in the first 2 or 3 early season sprays. For the control of overwintering generation of the plum curculio. Formulated with sulfur.
RAHAWG RAHAJC TBUCJA NASAVA QAMATA	Cottony peach scale (crawlers) Lecanium scale (crawlers) Oriental fruit moth Plum curculio Tarnished plant bug	[MAI] 0.375 lb/100 gal (5% WP)	Foliar application. May be applied in a complete spray schedule. Early ripening varieties will not require the full schedule of application. Formulated with sulfur.
		Also refer to Apricot cluster for additional pest and use information.	
	Pear		See Apple cluster.

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O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
03008AA	Pecan		0.5 ppm 21 day preharvest interval through 3.75 pounds per acre for foliar application. Do not graze livestock in treated groves. Do not use in home plantings.
RACAAA LAAABA	Aphids Mites (excluding spider mites)	0.3-0.5 lb/ 100 gal (25% WP) (2, 4, 5 lb/ gal EC) or 1-1.5 lb/A (4 lb/gal EC) [MAI] 2 lb/A (4 lb/gal EC)	Foliar application. Apply when pests first appear or when injury is first seen. Repeat as needed. May be formulated with parathion.
TABAIA TBDABA	Fall webworm Walnut caterpillar	0.375-0.5 lb/ 100 gal (25% WP) (2, 4, 5 lb/ gal EC) [MAI] 2 lb/A (4 lb/gal EC)	Foliar application. Apply while caterpillars are small. May be formulated with parathion.
TBGAXA NASBBA	Hickory shuckworm Pecan weevil	0.5 lb/100 gal (25% WP) or 0.375-0.5 lb/100 gal [250-500 gal/A] or 1.25-2.5 lb/A (2, 4, 5 lb/ gal EC) [MAI] 2 lb/A (4 lb/gal EC)	Foliar application. For hickory shuckworm, make first application at time of shell hardening or about August 10 to 15. Make 2 additional applications at 14 day intervals. This treatment will also control the pecan weevil. If pecan weevil is the only pest, make only 2 applications. Make first application about August 1 to 10 or when 6 or more weevils can be jarred from a single tree. Repeat 10 to 14 days later. May be formulated with parathion.

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pecan (continued)		
BPAEA	May beetles	0.375-0.5 lb/ 100 gal (25% WP) (2, 4, 5 lb/ gal EC)	Foliar application. Apply when beetles appear in the spring.
BMAFA	Pecan leaf case-bearer	0.4-0.5 lb/ 100 gal [250-300 gal/A] (25% WP) (2, 4, 5 lb/ gal EC) or 1.25-1.56 lb/A (5 lb/gal EC) [MAI] 2 lb/A (4 lb/gal EC)	Foliar application. Apply when pest first appears and repeat as needed. May be formulated with parathion.
TBMADA	Pecan nut case-bearer	0.3-0.5 lb/ 100 gal (25% WP) (2, 4, 5 lb/ gal EC) or 1-3.5 lb/A (4, 5 lb/gal EC) [MAI] 2 lb/A (4 lb/gal EC)	Foliar application. Apply when tips of small nuts begin to turn brown. Repeat at 7 to 10 day intervals as needed. May be formulated with parathion.
QAQALA	Southern green stink bug	0.375-0.5 lb/ 100 gal (25% WP) (2, 4, 5 lb/ gal EC)	Foliar application.
LAVAAA	Spider mites (including twospotted spider mite)	0.125-0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC) or	Foliar application. May be formulated with parathion.

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O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pecan (continued)		
		3-3.5 lb/A (4 lb/gal EC)	
		[MAI] 2 lb/A (4 lb/gal EC)	
RAEAAA	Spittlebugs	[MAI] 2 lb/A (4 lb/gal EC)	Foliar application. Apply when pest appears. If past experience indicates spittlebugs will be a problem, apply to the second prepollination spray. Formulated with parathion.
NALBCA	Twig girdler	0.375-0.5 lb/100 gal (25% WP) (2, 4, 5 lb/gal EC)	Foliar application. Make 3 applications at 14 day intervals beginning when damage appears. May be formulated with methyl parathion.
		[MAI] 2 lb/A (4 lb/gal EC)	
	Plum		See Apricot cluster.
	Prune		See Apricot cluster.
28023AA	Soybeans		0.05 ppm (negligible residue) 21 day preharvest, prefeeding and pregrazing interval through 1 pound per acre for foliar application.
IRACAAA	Aphids	[MAI] 0.25-0.52 lb/A (2, 3 lb/gal EC)	Foliar application. Formulated with methyl parathion.
ITBCCFA INAMARA	Armyworm Bean leaf beetle	[MAI] 0.5 lb/A (2 lb/gal EC)	
INBGAAA	Blister beetles	[MAI] 0.25-0.375 lb/A (2, 3 lb/gal EC)	

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Soybeans (continued)		
TBCCSA TBCCCA	Cabbage looper Green cloverworm	[MAI] 0.25-0.75 lb/A (2, 3 lb/gal EC)	
[TBCCZA [RASADA [TAAAMA	Climbing cutworms Threecornered alfalfa looper Webworms (including garden webworm)	[MAI] 0.125-0.52 lb/A (2, 3 lb/gal EC)	
[TBCCOC [TABACA	Fall armyworm (up to 3rd instar larvae) Saltmarsh caterpillar	[MAI] 0.5-1 lb/A (2, 3 lb/gal EC)	
[NAPAFA	Mexican bean beetle	[MAI] 0.25-1 lb/A (2, 3 lb/gal EC)	
IQAQAAA	Stink bugs	[MAI] 0.63-1 lb/A (2, 3 lb/gal EC)	
ILAVBEA ITBCATA	Twospotted spider mite Velvetbean caterpillar	[MAI] 0.2-0.375 lb/A (2, 3 lb/gal EC)	
ITBCBOA	Corn earworm	1 lb/A (4, 5 lb/gal EC) [MAI] 0.375-1 lb/A (2, 3 lb/gal EC)	Foliar application. Apply when larval counts show 1 larva per 3 feet of row. Repeat as needed. May be formulated with methyl parathion.

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
28020AA	Sugar Beets		3 ppm (roots) 21 day preharvest interval through 1 pound per acre for foliar application.
TBCCNA	Beet armyworm	1 lb/A (4, 5 lb/gal EC)	Foliar application.
TBMBWA	Beet webworm		
QAMACA	Rapid plant bug		
OABADA	Serpentine leafminer complex		
QAMATA	Tarnished plant bug		
MOAAAA	Thrips		
ILAVBEA	Twospotted spider mite		
11005AA	Tomato		3 ppm 3 day preharvest interval through 0.25 pound per acre for foliar application. 21 day preharvest interval from above 0.25 through 1 pound per acre for foliar application.
IRACAAA	Aphids	0.125-0.25 lb/A (25% WP) or 0.25-1 lb/A (2, 3, 4, 5 lb/gal EC)	Foliar application. Repeat at 7 to 10 day intervals as needed. May be formulated with methyl parathion.
ITBCDCA	Armyworm complex (including beet armyworm, southern armyworm, and yellowstriped armyworm)		
ITBCCSA	Cabbage looper		
INAMADA	Flea beetle	[MAI] 0.125-0.25 lb/A (2, 3 lb/gal EC)	
IRAFAAA	Leafhoppers		
IMAAAGA	Leafminers (including serpentine leafminer complex)		
IRACCHA	Potato aphid		
IRAXAAA	Psyllids		
IQAMACA	Rapid plant bug		
IQAMATA	Tarnished plant bug		
IMOAAAA	Thrips		
ITBCBOA	Tomato fruitworm		
ITBRAJA	Tomato hornworm		
ITBMANA	Tomato pinworm		
ILAJAHA	Tomato russet mite		
ILAVBEA	Twospotted spider mite		

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
03009AA	Walnut		0.5 ppm 21 day preharvest interval through 2 pounds per acre of wettable powder formulation or 3.5 pounds per acre of emulsifiable concentrate formulations for foliar application. Do not graze livestock in treated groves.
TBUCSA RACBHA	Codling moth Walnut aphid	0.25 lb/ 100 gal (25% WP) (4, 5 lb/gal EC) or 3-3.5 lb/A (4 lb/gal EC)	Foliar application. For codling moth, apply at petal fall and repeat at 10 to 14 day intervals as needed.
TBUAGA	Fruittree leaf-roller	0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 3-3.5 lb/A (4 lb/gal EC)	Foliar application.
LAVAAA	Spider mites (including European red mite, Pacific spider mite and twospotted spider mite)	0.125-0.188 lb/100 gal (25% WP) (4, 5 lb/gal EC) or 3-3.5 lb/A (4 lb/gal EC)	

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL NON-FOOD CROP		
	(General Soil Treatment and Composting)		
610170A	Earthworm Farms		30 day preharvest interval through 0.0416 ounce per 100 square feet for earthworm soil treatment. Do not make more than 2 applications per year. Wear protective rubber gloves during treatment and worm harvest. If earthworm pits are located indoors such as a utility building or barn, make sure to vacate the area of pets, fish, and wildlife. After treatment, close doors and leave closed for a 24 hour period. Thoroughly ventilate before reentry.
LBHABA	Red fishworm mite	0.0416 oz/100 sq.ft (0.26% G)	Earthworm soil treatment. Apply to earthworm enclosed soil pits. Distribute the granules evenly over the soil surface and follow with a light watering to move the granules into the soil surface. Red fishworm mite will be controlled for up to 30 to 40 days. Repeat if needed. If the soil has become heavily infested after treatments remove the soil and replace with new soil.
	AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS		
001500 AAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) All sites	
900300 AAAAAA	Tank Mix		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) All sites	

EPA Compendium of Acceptable Uses

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

Listing of Registered Pesticide Products by Formulation

&293.0001 93% technical chemical
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
003442-00681***007001-00348***
***voluntary cancellation

&280.0002 80% formulation intermediate
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
000352-00338***

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene range aromatic solvent (086803)
000876-00235***009566-00002***
***voluntary cancellation

&000.2604 0.26% granular
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
047056-00003

&001.0004 1% granular
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
019713-00120

&002.0004 2% granular
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
000876-00408 002393-00219 005905-00171 044215-00013

&004.0004 4% granular
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
000876-00407 002393-00232 005905-00181 008590-00625
034704-00059 044215-00021

&005.0006 5% wettable powder
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus sulfur or sulphur (077501)
000769-00382

&025.0006 25% wettable powder
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801)
000279-02675** 000769-00276 000876-00438 001842-00267
002169-00186*
*jacket currently unavailable for review
**suspended

&102.0012 2 lb/gal emulsifiable concentrate
O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus aromatic petroleum derivative solvent (006501)
005905-00101

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene (086802)
005905-00134

Listing of Registered Pesticide Products by Formulation (continued)

2 lb/gal emulsifiable concentrate (continued)

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene range aromatic solvent (086803)
005905-00191

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), aromatic petroleum derivative solvent (006501) plus O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501)
000769-00431

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), aromatic petroleum distillate (006601) plus O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501)
009779-00131 025030-00009

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501) plus xylene (086802)
001339-00220 001842-00268 005905-00107 013166-00010
044317-00024

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501) plus xylene range aromatic solvent (086803)
003442-00691 006735-00154

103.0012 3 lb/gal emulsifiable concentrate

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501)
010163-00093

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), aromatic petroleum derivative solvent (006501) plus O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501)
000769-00376

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), aromatic petroleum distillate (006601) plus O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501)
007467-00060 009779-00031 019713-00057 025030-00007
045115-00031

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), O,O-dimethyl O-p-nitrophenyl phosphorothioate (053501) plus xylene (086802)
001339-00219 001842-00265 005905-00085 012130-00010
013166-00007 044317-00030

Listing of Registered Pesticide Products by Formulation (continued)

3 lb/gal emulsifiable concentrate (continued)

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), 0,0-dimethyl O-p-nitrophenyl phosphorothioate (053501) plus xylene range aromatic solvent (086803)

000352-00406** 000876-00413 000876-00414 000876-00418
000876-00422 000876-00424 000876-00426 000876-00430
000876-00431 001063-00122 001191-00346* 001339-00222
001598-00248 002935-00349 003442-00694 004841-00065
004841-00066* 006735-00238* 007001-00351 008867-00041
032928-00010 033722-00013* 034704-00071 037686-00001
044605-00001

*jacket currently unavailable for review
**suspended

104.0012 4 lb/gal emulsifiable concentrate

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus aromatic petroleum distillate (006601)

009779-00032 044215-00008

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene (086802)

001990-00487* 002737-00017 005905-00174

*jacket currently unavailable for review

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene range aromatic solvent (086803)

000279-02650 000876-00433 002935-00346 006735-00142
008590-00594 019713-00130 034704-00061

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801), aromatic petroleum distillate (006601) plus parathion (057501)

009779-00213

105.0012 5 lb/gal emulsifiable concentrate

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus aromatic petroleum derivative solvent (006501)

000769-00359

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene (086802)

000876-00234 000876-00328* 001842-00264 005905-00123
005905-00349

*jacket currently unavailable for review

Listing of Registered Pesticide Products by Formulation (continued)

__5 lb/gal emulsifiable concentrate__ (continued)

O-ethyl O-(p-nitrophenyl) phenylphosphonothioate (041801) plus xylene range aromatic solvent (086803)

000352-00405** 000876-00359* 000876-00360 000876-00361
000876-00362 000876-00363 000876-00364 000876-00365
000876-00366 000876-00367 000876-00368 000876-00369
000876-00370 000876-00371 000876-00372 000876-00373
000876-00374 000876-00375 000876-00376 000876-00377
000876-00378 000876-00379 000876-00380 000876-00381
001386-00612 003442-00690 008590-00608 010107-00041
019713-00121 034704-00060

*jacket currently unavailable for review
**suspended

9999999 State Label Registrations

AL Reg. No.
009779-04760 015575-05331

CA Reg. No.
005967-05161 007001-07720

KS Reg. No.
002737-09563

LA Reg. No.
004841-06166

EPA Compendium of Acceptable Uses

O-ETHYL O-(p-NITROPHENYL) PHENYLPHOSPHONOTHIOATE

Appendix A-1

Listing of the Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
053501	methyl parathion (ISO)	O,O-dimethyl O-p-nitrophenyl phosphorothioate
057501	—	parathion
077501	sulfur	sulfur or sulphur

— Use EPA Acceptable Common/Chemical Name

IV. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the EPN Standard

MRID	CITATION
00002875	Frear, D.E.H.; Boyd, J.E. (1967) Use of Daphnia magna for the microbioassay of pesticides: I. Development of standardized techniques for rearing Daphnia and preparation of dosage-mortality curves for pesticides. Journal of Economic Entomology. 60(5):1228-1236. (Also in unpublished submission received May 11, 1977 under 239-2458; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:230225-A)
00003945	Cuthbert, F.P., Jr.; Reid, W.J., Jr. (1962) Laboratory Tests of Compounds for Toxicity to Larvae of the Banded Cucumber Beetle. By U.S. Agricultural Research Service, Entomology Research Division. Washington, D.C.: U.S. Dept. of Agriculture. (ARS-33-72; also in unpublished submission received on unknown date under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:008870-B)
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00036935	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)
00057028	Tayfun, F.O. (1971) One-Hour Inhalation Toxicity: Haskell Laboratory Report No. 32-71. (Unpublished study received Mar 21, 1977 under 352-338; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:228727-B)
00066341	U.S. Environmental Protection Agency, Environmental Research Laboratory (1981) Acephate, Aldicarb, Carbophenothion, DEF, EPN, Ethoprop, Methyl Parathion, and Phorate: Their Acute and Chronic Toxicity, Bioconcentration Potential, and Persistence as Related to Marine Environments: EPA-600/4-81-023. (Unpublished study)
00068367	E.I. du Pont de Nemours & Company (1951) Residues of EPN on Food Crops. (Unpublished study received on unknown date under 352-146; CDL:231094-B)

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MRID	CITATION
00068437	E.I. du Pont de Nemours & Company (1961) EPN 300 Insecticide: Experimental Results. (Reports by various sources; unpublished study, including published data, received on unknown date under 352-146; CDL:231099-A)
00068905	E.I. du Pont de Nemours & Company (1978) Residue Analysis (1977 Results). (Compilation; unpublished study received Jun 15, 1978 under unknown admin. no.; CDL:234119-G)
00077299	Fink, R. (1976) Final Report: Eight-Day Dietary LC50--Mallard Duck: Project No. 107-128. (Unpublished study received Aug 31, 1976 under 876-235; prepared by Truslow Farms, Inc., submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:226817-A)
00079794	Fisher, R.L. (1978) Letter sent to J.A. Gardiner dated Aug 30, 1978: Metabolism of 14C-EPN in chickens. (Unpublished study received on unknown date under 352-338; submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:236741-J)
00079807	E.I. du Pont de Nemours & Company, Incorporated (1977) Technical Manual for Insecticide Formulators: EPN Technical. Wilmington, Del.: DuPont. (Also in unpublished submission received on unknown date under 352-338; CDL:236741-X)
00085219	Sanders, H.O. (1972) Toxicity of Some Insecticides to Four Species of Malacostracan Crustaceans. By U.S. Fish and Wildlife Service, Fish-Pesticide Research Laboratory. Washington, D.C.: USFWS. (Technical papers of the Bureau of Sport Fisheries and Wildlife 66; published study; CDL:232666-T)
00085429	E.I. du Pont de Nemours & Company (1978?) Summary of Preliminary Studies on the Hen Metabolism of EPN at a High Dose Level. Summary of study 236741-L. (Unpublished study received on unknown date under 352-338; CDL:236741-K)
00089025	E.I. du Pont de Nemours & Company (1972) Residue Analyses of Tark Mix Combinations of EPN + Lannate Insecticide on Cotton. (Unpublished study received May 29, 1981 under 352-342; CDL:246524-B)
00100078	E.I. du Pont de Nemours & Co., Inc. (1950) Residue Data for EPN 300 Insecticide on Various Fruit. (Compilation; unpublished study received Oct 14, 1950 under 352-146; CDL:002747-D)
00100088	Anon. (19??) Residue Data EPN on Sweetcorn. (Unpublished study received on unknown date under unknown admin. no.; submitted by ?; CDL:124392-A)

OFFICE OF PESTICIDE PROGRAMS
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MRID CITATION

00100090 E.I. du Pont de Nemours & Co., Inc. (1959) Data Supporting Revised Use Claims for EPN 300 Insecticide on Tomatoes. (Unpublished study received Feb 26, 1959 under unknown admin. no.; CDL: 124557-A)

00100093 Union Carbide Corp. (1976) Acute Toxicity of EPN (80% Active Ingredient) to Bluegill Sunfish ..., Rainbow Trout ..., and the Water Flea Daphnia Magna Straus. (Unpublished study received Apr 26, 1976 under 876-235; submitted by Velsicol Chemical Corp., Chicago, IL; CDL:223991-B)

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00109147 Chrzanowski, R. (1977) Metabolism of 14C-EPN on Cotton Plants. (Unpublished study received Dec 1, 1977 under 352-338; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, DE; CDL: 232389-C)

00111931 Fink, R. (1976) Final Report: Acute Oral LD50--Mallard Duck: Technical EPN: Project No. 107-129. (Unpublished study received Apr 26, 1976 under 876-235; prepared by Truslow Farms, Inc., submitted by Velsicol Chemical Corp., Chicago, IL; CDL:223991-A)

00145678 Dean, W. (1977) Acute Dermal Toxicity (LD50) Study in Albino Rabbits: Study No. 163-495. Unpublished study prepared by International Research and Development Corp. 18 p.

00152760 Cox, R.; Dean, R.; Quander, R.; et al. (1985) 21-day Dermal Toxicity Study in Rats: EPN Technical: Final Report: Project No. 2096-120. Unpublished study prepared by Hazleton Laboratories America, Inc. 145 p.

00153508 Kennelly, J. (1985) Study To Determine the Ability of EPN Technical To Induce Unscheduled DNA Synthesis in HeLa Cells: Study No.: NCJ 1/He/KF16/HE2. Unpublished study prepared by Microtest Research Ltd. 16 p.

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MRID	CITATION
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00153510	Kirkland, D. (1985) Study To Evaluate the Chromosome Damaging Potential of EPN Technical by Its Effects on Cultured Chinese Hamster Ovary (CHO) Cells Using an in Vitro Cytogenetics Assay: Study No.: NCJ 1/CHO/KF17/CH3. Unpublished study prepared by Microtest Research Ltd. 21 p.
00153511	Kennelly, J. (1985) Study To Determine the Ability of EPN-Technical To Induce Mutation in Four Histidine-requiring Strains of Salmonella typhimurium: Study No.: NCJ 1/S/AF4/SA3. Unpublished study prepared by Microtest Research Ltd. 33 p.
00158890	Osheroff, M. (1986) Subchronic Toxicity Study in Dogs: [Using EPN Technical]: Final Report: Project No. 2096-121. Unpublished study prepared by Hazleton Labs. America, Inc. 232 p.
00158920	Cresswell, D.; Hopkins, R. (1986) [Carbon-14]-EPN: A Study of the Absorption, Distribution, Metabolism and Excretion in the Rat: Report No. 4958-306/14. Unpublished study prepared by Hazleton Laboratories Europe Ltd. 561 p.
00159372	Roberts, N.; Phillips, C.; Gopinath, C.; et al. (1986) Acute Delayed Neurotoxicity Study with EPN in the Domestic Hen: Report No. NSA 19(a)/8646. Unpublished study prepared by Huntingdon Research Centre Ltd. 50 p.
00160200	Roberts, N.; Phillips, C. (1986) Acute Delayed Neurotoxicity Study with EPN in the Domestic Hen, Providing Additional Information on Recovery Aspects: NSA 19 (b)/86335. Unpublished study prepared by Huntingdon Research Centre Ltd. 101 p.
00160618	Kennelly, J. (1986) Study To Determine the Ability of EPN Technical To Induce Mutations to 6-Thioguanine Resistance in Mouse Lymphoma L5178y Cells Using a Fluctuation Assay: Study No. NCJ 1/ML/KF20/ML3. Unpublished study prepared by Microtest Research Ltd. 26 p.
00161799	Collins, C. (1986) EPN Technical: 13 Week Inhalation Toxicity Study in the Rat: Report No. 5160-306/13. Unpublished study prepared by Hazleton Laboratories Europe, Ltd. 206 p.

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MRID	CITATION
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00162999	Ruhland, J. (1986) Determination of Dislodgeable Residues of EPN, EPN Oxon, and EPN S-ethyl from Corn, Soybean, Cotton, Pecan, and Citrus Foliage (Analytical Results): Cotton Repeat: Addendum B to the Final Report: Study No. 6157-124. Unpublished study prepared by Hazleton Laboratories America, Inc. 89 p.
00163019	Morseth, S. (1986) Rabbit Teratology Study EPN Technical: Final Report: Project No. 2096-116. Unpublished study prepared by Hazleton Laboratories America, Inc. 149 p.
00163515	Ruhland, J. (1986) Determination of the Dislodgeable Residues of EPN, EPN Oxon, and EPN S-Ethyl from Corn, Soybean, Cotton, Pecan, and Citrus Foliage (Analytical Results): Stability Study: Interim Addendum A to the Report: Study No. 6157-124. Unpublished study prepared by Hazleton Laboratories America, Inc. 96 p.
05000975	Tucker, R.K.; Haegele, M.A. (1971) Comparative acute oral toxicity of pesticides to six species of birds. Toxicology and Applied Pharmacology 20(1):57-65.
05008363	Hudson, R.H.; Haegele, M.A.; Tucker, R.K. (1979) Acute oral and percutaneous toxicity of pesticides to mallards: correlations with mammalian toxicity data. Toxicology and Applied Pharmacology 47(3):451-460.
05009242	Sanders, H.O. (1969) Toxicity of Pesticides to the Crustacean Gammarus lacustris:. Washington, D.C.: U.S. Bureau of Sport Fisheries and Wildlife. (U.S. Bureau of Sport Fisheries and Wildlife technical paper 25)
GS0147-001	Horwitz, W. ed. (1980) Officeial Methods of Analysis of the Association of Official Analytical Chemists: 13th ed. Washington, D.C.: A.O.A.C. (Section 29.039-29.043 only.

V. FORMS APPENDICES

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ **1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:**

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ **2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:**

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ **3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:**

☐ **4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):**

☐ **5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)**

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ________________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________________

Date ______________ Title ______________________________

EPA Form (April 1985)